COMPETITIVENESS AND INNOVATION FRAMEWORK PROGRAMME

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D6.4 – Ethical Guidelines Report

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[1] Please use a new number for each new version of the deliverable. Add the date when this version was issued and list the items that have been added or changed. The 'what's new' column will help the reader in identifying the relevant changes. Don't forget to update the version number and date on the front page and the header.
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Executive Summary

Introduction

To successfully develop the LLM service and run the pilot studies, the LLM consortium must be able to identify potential ethical, privacy and security risks and know what to do to avoid or minimize those same risks. This Ethical Guidelines Report (D6.4) discusses the legislation and guidelines that must be followed throughout the project in order to protect the basic human rights (such as privacy and dignity) of all LLM users. Considerations that should be regarded during the life of the project are explicitly discussed, including assurances regarding the anonymity of the test and end-users of LLM, as well as protection of the collected data.

The LLM project partners stress the importance of remaining aware of potential risks in all facets of the LLM research throughout its lifetime. The partners further acknowledge that it may be necessary to resolve ethical issues that arise during the course of the LLM project by making choices on the basis of principles and values. Therefore, it is necessary to first define the emerging ethical concerns that may arise at any time throughout the lifetime of the project and also during the final dissemination phase.

The structure and key contents of the deliverable

This document outlines the set of basic principles that the LLM project partners should aim to adhere to when making balanced ethical decisions during the life of the project. This document details the ethical framework that will be adopted to influence the technical and business exploitation choices that could arise during the pilots' design and the implementation of the LLM service. It then further considers strategies to address those potential ethical issues.

The overall intent of this deliverable is to present and discuss the ethical issues associated with the development of the LLM technology, as well as those ethical issues that may impact the business planning of the final marketable product.

Note that this document focuses on the strategies that will be implemented in the LLM pilot studies and final integrated service to address the ethical directives already outlined and discussed in detail in the LLM deliverable D6.1: Report on National and European Legislation. The actual directives will not be discussed again in this document. However, it is expected that this deliverable D6.4 be used in conjunction with deliverable D6.1 to provide the complete ethical framework to be used throughout the project.

Please note also that although this document includes references pertaining to "clinical studies," the LLM trials are not medical clinical trials and thus do not require any specific actions to comply with the regulations for clinical trials in accordance with LLM pilot country legislation. All clinical trial regulation and legislation references have been included only to maintain the highest level of integrity of the study and to ensure that the pilots will adhere as closely as possible to those standards to ensure quality of the data collected and to provide for all appropriate protections of individuals (and their personal data) participating in the pilots.

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1 Key Ethical Issues Involved in LLM

1.1 About LLM

1.1.1 The LLM Service

The driving purpose behind the development of LLM is to enable older citizens to live at home independently for longer periods of time, supporting those efforts with a system that builds on the idea of protecting the elderly against the development of dementia and other memory-related illnesses, through cognitive and physical exercises. The LLM service will aid the elderly in their everyday life and help them improve their overall well-being.

As shown in Figure 1 below, the LLM service will be comprised of three integrated interoperable components that perform complementary and interactive tasks to provide the system's services.

Figure 1: The LLM Service

The ultimate aim of the LLM service is to deliver innovative ageing well / independent-living support services for elders. The service adaptation will be divided into two distinct tasks:

1. integrating the three components
2. localizing the service to the countries where it will be piloted

The three LLM components are as follows:

- The **Independent Living Component (ILC)** is based on the eHome system, which is a network of distributed, wirelessly-operating sensors connected to an embedded system (the e-Home central unit). It includes features, such as intelligent learning of normal and exceptional patterns of behaviour (dangerous situations or indicators for emerging health problems), and relevant alarms. e-Home is a project funded by the Austrian Research Promotion Agency (FFG). The ILC is responsible for assisting seniors living an independent life by monitoring their daily activity and responding by initiating alarms where emergency cases are identified.

- The **Cognitive Training Component (CTC)** is designed to support cognitive exercises provided by specialised software to help elderly people to improve their cognitive capacity or mental health, by aiming to enhance several functionalities of the human brain. A variety of software can be used for this process; a careful evaluation has been performed by the LLM partnership to identify the appropriate software for testing during the project and for completing customization and localization of this software as needed for the initial deployment and the pilot testing of the LLM system.
- The **Physical Training Component (PTC)** comprises custom training equipment, which is geared to meet the specialised needs of the elderly to motivate them to exercise themselves in a more convenient and enjoyable way. The only prerequisite for the equipment selected for integration is that it is able to provide exercise performance output. This output will be forwarded to the central LLM system for monitoring and processing.

1.1.2 LLM Users

LLM will be used by four types of users: the elderly, their therapists, the relatives of the elderly people who mainly access the system in order to keep track on the progress of their older relatives, and the LLM administrators. The LLM system, installed at the user's home, monitors all their movement and activities. The user can access the system through touch-screens placed at preferred locations around the house.

LLM users can also be categorized as "pilot users" and "final product users." For the purposes of this ethical guidelines discussion, those two types of users will not be distinguished. The ethical issues considered will be the same for both.

All users are given a single account which they use to log into the LLM system. After they log into the system, they are assigned a unique role that allows certain actions (e.g., rights) on certain system objects. The user can select an activity type, like checking the latest news on the simplified web browser, turning on the TV, etc. Alternatively, the user can initiate a training program, either cognitive or physical, and subsequently perform the exercises. The therapists also have access to the LLM system and can query the system to print reports on the (elderly) users' activities. The therapists and the system itself can create a daily schedule of all the activities to be carried out by the elderly users. During the training activities, the system can recognize emergency cases that elderly users may face during their session and notify therapists or relatives through alerts. Alerts will be triggered under emergency conditions (such as the elderly user falling down or the overheating of an electrical appliance), at which point the system can call an ambulance, send SMS notifications, and/or call the therapists and the user's relatives. Finally, the relatives can have a constant update on the progress of the elderly users through notifications (e.g. to their mobile phones) and/or through reports (e.g. daily, weekly, monthly).

1.2 Ethical Issues and Principles

The success of the LLM project depends greatly on having all project partners being aware of the ethical challenges involved in the implementation. To successfully develop the LLM service and run the pilot studies, the LLM consortium must be able to identify potential ethical, privacy and security risks and know what they must do in order to avoid or minimize those same risks.

The specific ethical issues addressed in this document, and to be monitored throughout the LLM project lifetime, include the following:

- **Anonymity** – One common definition of this term is to "remain nameless." In terms of the LLM project, the ethical principal of anonymity pertains to participating in the study but doing so without one's name being known. Additionally, all collected data processed for statistical and/or scientific purposes shall also not be identifiable to the participant from whom it was gathered.

- **Dignity and independence** – the claim of individuals, groups or institutions to determine for themselves when, how, and to what extent information about them is communicated to others. The principle of dignity is related to the belief that intrinsic worth inheres in every human being. In regards to research ethics, the project must do everything it can to guarantee the dignity of all participants.

- **Free and fully informed consent** – Informed consent allows the LLM pilot study participant to be fully aware of the procedures, benefits, potential risks, and technological and privacy implications that may be involved in the pilot. A consent form provides sufficient details regarding the study in the simplest manner and ensures that the signee understands all phrasing regarding the pilot consequences in order to make a fully informed decision as whether or not to participate. The consent form is an agreement between the study participant and the researcher to ensure that there is no coercion for the prospective participant to become involved with the study.

- **Objectivity** – This ethical principle pertains to the goal of avoiding or minimizing bias or self-deception in research studies. Objectivity must be sought after in the research design, data analysis and interpretation, peer reviews, audits, staff decisions, and other aspects of research where objectivity is expected or required.

- **Processing, protection and confidentiality of personal data** - Under the Data Protection Act 1998 'personal data' is defined as data which relates to a living individual who can be identified a) from those data or, b) from those data and other information which is in the possession of, or is likely to come into the possession of, the data controller, and includes any expression of opinion about the individual and any indication of the intentions of the data controller or any other person in respect of the individual.

  In terms of the LLM project, the ethical responsibility of processing, protecting and ensuring the confidentiality of personal data falls to all LLM staff members who have

access to any collected personal data. It must be guaranteed that all appropriate measures must be implemented to protect this personal data against accidental or unlawful destruction or accidental loss, alteration, unauthorised disclosure or access.

Where the data are contained in lists, registers, and/or electronic databases, they shall be processed by using either encryption techniques or identification codes and/or other solutions that make said data temporarily unintelligible also to those entities that are authorised to access them and allow identifying data subjects only if this is necessary.

The processing of all personal data and any health-related sensitive data will be performed in strict adherence to all relevant data protection legislation as outlined in LLM deliverable D6.1: Report on National and European Legislation.

- **Nonmaleficence and Safety –** While nonmaleficence imparts an obligation to not inflict harm intentionally, safety involves freedom from danger. In terms of the LLM project, every pilot participant and system user must be guaranteed the right to be safe and free of harm while using the system. All harms and risks must be minimized, with special precautions being taken for vulnerable populations.

- **Self-determination** – The right of self-determination is generally defined as a person's right to make decisions that affect his or her own actions. In terms of the LLM project, this right translates to the ethical principle that allows participants to opt into or out of the project at any time, as well as control the data that pertains to them.

- **Respect for Autonomy** - Autonomy is the capacity for self-determination and freedom from any limitations that prevent adequate understanding of choices and the freedom to make meaningful choices. Autonomy requires the participant's independence from any controlling influences by others that may prevent a meaningful choice. In terms of the LLM project, the participant or LLM user must be given the right to overrule or switch off the technology (as built into the system), to opt out completely from participating, and/or to pull their trial data from the results, should they so wish.

In addition to the ethical issues noted above, The Economic and Social Research Council (ESRC) of the UK has defined six key principles[3] of ethical research that should be addressed when applicable. The LLM project will adhere to all of the following six principles:

1. Research should be designed, reviewed and undertaken to ensure **integrity**, **quality** and **transparency**.
2. Research staff and participants must normally be **informed fully** about the purpose, methods and intended possible uses of the research, what their participation in the research entails and what risks, if any, are involved.
3. The **confidentiality of information** supplied by research participants and the **anonymity of respondents** must be respected.

[3] http://www.esrc.ac.uk/ESRCInfoCentre/Images/Framework%20for%20Research%20Ethics%202010_tcm6-35811.pdf

4. Research participants must take part **voluntarily**, free from any coercion.
5. Research participants must be **free from harm** in all instances.
6. The independence of research must be **clear**, and any conflicts of interest or partiality must be explicit.

2 Ethical Legislation and Guidelines

2.1 European Ethical Legislation and Guidelines

In an effort to protect its citizens, the EU has implemented many directives and guidelines that have some component of ethical obligation and direction regarding the protection of citizen human rights and the privacy and confidentiality of personal data.

The directives listed below are those that impact the conduct of the LLM project development and pilot studies. Each is discussed in detail in the LLM deliverable, D6.1: Report on National and European Legislation.

- Charter of Fundamental Rights of the European Union[4]
- The European Human Rights Convention[5]
- European Commission's Seventh Framework Programme (2007-2013)[6]
- Directive 95/46/EC of the European Parliament and of the Council[7]
- Directive 2002/58/EC[8]
- World Medical Association Declaration of Helsinki[9]
- Convention for the Protection of Individuals with regard to Automatic Processing of Personal Data (ETS No. 108)[10]
- Convention for the Protection of Human Rights and Dignity of the Human Being with Regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine CETS No.: 164 (1997)[11]
- Clinical Trial Directive 2001/20/EC[12]
- GCP CPMP/ICH135/95[13] (Annex to Directive 75/318/EEC as amended)
- Directive 97/66/EC[14]

[4] Official Journal of the European Communities, The Charter of Fundamental Rights of the European Union (2000/C 364/01), 18 December 2000. http://www.europarl.europa.eu/charter/pdf/text_en.pdf
[5] European Court of Human Rights, Convention for the Protection of Human Rights and Fundamental Freedoms, 4 November 1950. http://conventions.coe.int/treaty/en/Treaties/Html/005.htm
[6] Official Journal of the European Union, Decision No. 1982/2006/EC of the European Parliament and of the Council, 18 December 2006. http://eur-lex.europa.eu/LexUriServ/site/en/oj/2006/l_412/l_41220061230en00010041.pdf
[7] Official Journal of the European Communities, Directive 95/46/EC of the European Parliament and of the Council, 24 October 1995. http://ec.europa.eu/justice_home/fsj/privacy/docs/95-46-ce/dir1995-46_part1_en.pdf
[8] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2002:201:0037:0047:EN:PDF
[9] World Medical Association Declaration of Helsinki , 59th WMA General Assembly, Seoul, October 2008. http://www.wma.net/en/30publications/10policies/b3/index.html
[10] http://www.litbang.depkes.go.id/ethics/knepk/kegiatan/basic/declarat/datprotcon.htm
[11] http://shr.aaas.org/article15/Reference_Materials/CoE_Conv_on_HRs_and_Biomedicine_Eng.pdf
[12] Official Journal of the European Communities, Directive 2001/20/EC, 4 April 2001. http://www.wctn.org.uk/downloads/EU_Directive/Directive.pdf
[13] European Medicines Agency, Guideline for Good Clinical Practice. http://ec.europa.eu/enterprise/pharmaceuticals/eudralex/vol-10/3cc1aen.pdf
[14] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:1998:024:0001:0008:EN:PDF

Specifically, the Charter of Fundamental Rights of the European Union, referenced above, has established the following general ethical principles as fundamental rights for citizens of Europe:

The respect for:

- human life,
- human dignity, integrity of the person,
- democracy, the rule of law,
- prohibition of inhuman or degrading treatment,
- cultural, religious and linguistic diversity,
- equality and no discrimination,
- freedom of expression and of information,
- the freedom of arts and research,
- property and intellectual property,
- health care,
- consumer protection,
- the right of the child, the elderly and the handicapped,
- environment,
- privacy, protection of personal data, also genetic data,
- liberty and security.

The LLM project will respect all of these ethical guidelines that pertain to the LLM pilot study and implemented service.

2.2 European Ethics Groups and Committees

In addition to the legislation and directives noted above, various groups and committees pertaining to ethics in research have been established throughout Europe in an effort to protect its citizens.

2.2.1 European Network of Research Ethics Committees (EUREC)[15]

EUREC is a network of national networks and associations of Research Ethics Committees (RECs) in Europe. The network aims at the development of high quality standards in clinical trials in order to protect human subjects.

Representatives from national associations of RECs decided to work together in order to maintain and develop high quality standards in the protection of human subjects in Europe. As a result, on 27, January 2005, they formed EUREC to do the following:

- facilitate exchanges of knowledge, know-how and information
- disseminate training materials among members of RECs, and
- conduct research on characteristics of biomedical research conducted on human beings.

[15] http://www.eurecnet.org/index.html

2.2.2 European Group on Ethics in Science and New Technologies (EGE)[16]

In November 1991, the European Commission set up a Group of Advisers on the Ethical Implications of Biotechnology (GAEIB) in an attempt to incorporate ethics into the decision-making process for community research and technological development policies. In December 1997, the Commission replaced GAEIB with a new group called the European Group on Ethics in Science and New Technologies (EGE), which extended the original GAEIB's mandate to cover all areas of the application of science and technology.

EGE is composed of fifteen experts, all of whom have been appointed by the President of the European Commission and represent a broad range of professional competencies.

The group is responsible for advising the European Commission on ethical questions relating to sciences and new technologies, either at the request of the Commission or on its own initiative. The Opinions issued by the group are disseminated publicly and include an overview of the debated issue, the ethical concerns, and the recommendations for responsible policymaking consistent with societal needs.

EGE opinions and other publications can be accessed from the following websites:

- http://ec.europa.eu/european_group_ethics/avis/index_en.htm
- http://ec.europa.eu/european_group_ethics/publications/index_en.htm

2.2.3 European Commission, Seventh Framework Programme Ethical Guidelines[17]

To ensure to citizens and decision-makers that EU-funded research complies with the highest standards, fundamental ethical principles have been established for all research activities funded under the European Commission's Seventh Framework Programme.

The Ethical Guidelines for undertaking ICT research in FP7[18] states the following:

> "The decision of the European Parliament and the Council concerning FP7 states that research activities supported by the Framework Programme should respect fundamental ethical principles, including those reflected in the Charter of Fundamental Rights of the European Union and take into account opinions of the European Group on Ethics in Science and New Technologies (EGE).
>
> Article 15 of the FP7 Rules for Participation states that any proposal which contravenes fundamental ethical principles or which does not fulfil the conditions set out in the specific programme, the work programme or in the call for proposals shall not be selected and may be excluded from the evaluation, selection and award procedures at any time.

[16] http://ec.europa.eu/european_group_ethics/index_en.htm
[17] http://cordis.europa.eu/fp7/ethics_en.html
[18] ftp://ftp.cordis.europa.eu/pub/fp7/docs/guidelines-annex5ict.pdf

Applications for EU-funded research activities may, if appropriate, include specific tasks or a specific work package that explicitly addresses ethical concerns (in terms of the research, its conduct and outcomes) and outlines how ethical issues raised by the proposed research will be handled."

The FP7 Guide for Applicants also includes an Ethical Issues Table as illustrated in Figure 2 below:

ETHICAL ISSUES TABLE

	YES	PAGE
Informed Consent		
• Does the proposal involve children?		
• Does the proposal involve patients or persons not able to give consent?		
• Does the proposal involve adult healthy volunteers?		
• Does the proposal involve Human Genetic Material?		
• Does the proposal involve Human biological samples?		
• Does the proposal involve Human data collection?		
Research on Human embryo/foetus		
• Does the proposal involve Human Embryos?		
• Does the proposal involve Human Foetal Tissue / Cells?		
• Does the proposal involve Human Embryonic Stem Cells?		
Privacy		
• Does the proposal involve processing of genetic information or personal data (e.g. health, sexual lifestyle, ethnicity, political opinion, religious or philosophical conviction)		
• Does the proposal involve tracking the location or observation of people?		
Research on Animals		
• Does the proposal involve research on animals?		
• Are those animals transgenic small laboratory animals?		
• Are those animals transgenic farm animals?		
• Are those animals cloned farm animals?		
• Are those animals non-human primates?		
Research Involving Developing Countries		
• Use of local resources (genetic, animal, plant etc)		
• Benefit to local community (capacity building i.e. access to healthcare, education etc)		
Dual Use		
• Research having direct military application		
• Research having the potential for terrorist abuse		
ICT Implants		
• Does the proposal involve clinical trials of ICT implants?		
I CONFIRM THAT NONE OF THE ABOVE ISSUES APPLY TO MY PROPOSAL		

Figure 2

2.2.4 European Commission, DG Research, Unit L3: Governance and Ethics[19]

The EC Governance and Ethics Unit aims to define and implement a research strategy and agenda in the areas of open governance of science, democracy, fundamental rights and ethics across Europe and beyond in the context of the 7th Research Framework Programme (FP7).

Some of its main tasks pertaining to ethics include: Implementing the ethical review and ethics audits of funded research projects under FP7; enhancing the understanding of ethical issues in research and fostering transnational debates; supporting networking of ethics councils and committees; and favouring good governance and ethics practices in specific research and development fields.

2.3 National Professional Ethics Committees

In addition to the groups and committees that have been established to protect the rights of citizens in all of Europe, every individual country represented by an LLM consortium partner has its own legislation and committees to further protect the citizens of their nation and to eliminate any harm to which they may be exposed during research and science advancements.

A list of the ethics committees of all Member States and other countries can be found at the following site:

http://ec.europa.eu/european_group_ethics/link/index_en.htm#4

The table below lists the national professional ethics committees that provide ethical guidances in the LLM partner countries.

Table 1: National Professional Ethics Committees

LLM Partner Country	Ethics Committees and Guidelines
Austria	Austrian Commission on Bioethics
Cyprus	The Cyprus National Bioethics Committee (CNBC)
France	National Consultative Committee of Ethics
Germany	The Deutsche Forschungsgemeinschaft The Zentrale Ethikkommission The German National Ethics Council Inquiry of the Commission of the German Parliament on Law and Ethics in Medicine

[19] http://ec.europa.eu/research/conferences/2009/rtd-2009/documentation/science_economy_and_society/governance_and_ethics.pdf

Table 1: National Professional Ethics Committees	
LLM Partner Country	**Ethics Committees and Guidelines**
Greece	The National Bioethics Committee Hellenic Center for Biomedical Ethics
Spain	Spanish Bioethics Commission
UK	Economic and Social Research Council (ESRC) Nuffield Council on Bioethics Human Genetics Commission British Psychological Society Code of Conduct and Ethical Guidelines Department of Health Research Governance The Ministry of Defence Research Ethics Committee (MODREC) UK Research Integrity Office: Code of Practice for Research National Research Ethics Service Research Councils UK (RCUK) Governance of Good Research Conduct Social Care Research Ethics Committee Social Research Association Ethical Guidelines

3 E-Inclusion and Best Practice Considerations for ICT

3.1 Ethics and E-Inclusion

> *Europeans are living longer than ever thanks to economic growth and advances in health care. Average life expectancy is now over 80, and by 2020 around 25% of the population will be over 65. Fortunately, the Information Society offers older people the chance to live independently and continue to enjoy a high quality of life. Currently, however, a number of barriers prevent the older generation from fully embracing Information and Communication Technologies (ICT). In response, the European Commission is developing actions to improve ICT uptake amongst the elderly.*[20]

This statement by the European Commission makes it clear that we must develop ICT to be used by the elderly in an attempt to foster e-inclusion; however, the ethical challenges to doing so cannot be ignored. ICT for the elderly has the potential to increase the number of elderly persons in the workforce, as well as enable the elderly to live independently for longer periods of time. When developing ICT for the elderly, all ethical issues identified earlier in this document still apply – informed consent, right to privacy and protection of personal data, respect for dignity and integrity, non-intrusiveness, and autonomy. However, there are additional product design considerations that must be addressed to ensure that the ICT is inclusive and, while at the same time, protecting the aforementioned ethical rights of the user. For example, can the user easily opt out of certain default settings? Does the user fully understand the product controls and options? Is the product designed for easy use by all?

The LLM service will address these ethical considerations in its design, including characteristics such as usability, accessibility, and understandability by its end users. Moreover, it will take into consideration the common e-accessibility barriers senior citizens face, such as ability restrictions concerning cognition, vision, hearing, and mobility dexterities. To address these restrictions, special attention will be paid concerning the design of the LLM user interface. Several aspects to be taken into consideration during the development process include:

- conformance with international e-accessibility guidelines (WCAG) for content development (e.g. large buttons), and
- provision of alternative multimedia content for specific objects.

The LLM terminal devices that will be used, such as touch screens, are widely considered to be an easy to use communication means by elderly people who have no prior computer experience. These, in combination with user-friendly remote controllers, such as Nintendo Wii Remote, constitute a set of input devices particularly popular to seniors that can be used on a daily basis and contribute to the ease of accessibility to the services offered by LLM system to end users.

Additionally the LLM system will enforce e-accessibility to the information offered by

[20] http://ec.europa.eu/information_society/activities/einclusion/policy/ageing/index_en.htm

LLM services by transforming computer use from just a simple tool into a personal companion, accompanying elderly people in their daily activities, thus encouraging, motivating them and providing them with some sort of social interaction.

Finally, the creation of a daily schedule by a decision support system supported by the LLM system according to seniors' performance in several kind of training will help seniors to focus on the exercises to be performed and to avoid possible confusion.

3.2 Ethics and Best Practices

The European Commission staff working paper "Science, society and the citizen in Europe"[21] advocates the consideration of ethical issues and societal concerns in research practices. The central focus of the document is how to implement research policy around the real aims of society and fully involve society in seeing through the research agenda. Specifically, the document states:

> *"The relationship between science and society today is something of a paradox. First of all, science and technology are at the heart of the economy and society, and both are having an increasingly positive effect on the lives of people in Europe… Conversely, advances in knowledge and technology are greeted with growing skepticism, even to the point of hostility, and the quest for knowledge no longer generates the unquestioning enthusiasm that it did some decades ago. Searching questions are being asked of the social and ethical impact of the forward march of knowledge and technology and the conditions under which the basic choices are made (or are not made) in this area."*

In other words, all technology being funded and developed must be considered in light of the impact it has on society and on those to whom it is expected to benefit. We can no longer simply develop new technology for the sake of technology alone. New ICT must make a positive contribution to the economy, society and personal quality of life.

One way in which to ensure that new technology is being developed in an ethical and responsible manner, and at the same time foster e-inclusion, is to consider the ICT in light of "best practices." "Best practices" or "good practices" are those techniques or methods that have been identified as delivering the best outcome to a given situation. Best practices may become standards of efficiency and effectiveness in an organization; however, they may also continue to be modified and refined as new best practices are proven.

The European Commission has a good practice portal (ePractice.eu[22]) where members can submit their good practice case suggestions and ideas. As of May 2010, the portal has accumulated and published more than 1,300 good practice cases since its launch in June 2007. ePractice.eu cases are written summaries of real-life projects or business solutions developed

[21] ftp://ftp.cordis.europa.eu/pub/rtd2002/docs/ss_en.pdf
[22] http://epractice.eu/

by public administrations, entrepreneurs and corporations, pertaining to eGovernment, eInclusion, and eHealth.

The SENIOR project[23], funded by the European Commission under its Seventh Framework Programme (FP7), was a 24-month support action aimed to provide a systematic assessment of the social, ethical and privacy issues involved in ICT and Ageing, to understand what lessons should be learned from current technological trends, and to plan strategies for governing future trends. The project identified ICT services and solutions that avoid exclusion and promote inclusion of senior citizens and developed a roadmap showing how ethics and privacy principles could be incorporated in technology design.

Some best practice suggestions for ICT design are listed below. The second column also notes whether the suggestion is to be incorporated into the LLM design.

Best practice suggestion	Included in LLM design?
Informed consent as to participation and project result must be required.	√
Participation must be voluntary.	√
Prospective users should be involved with the design and testing.	√
Projects are more likely to succeed where they are well rooted in the needs of stakeholders.	√
Participation must be equal amongst all.	√
The language used must be inclusive.	√
Designs must be universal, intuitive, easy-to-use, and follow the "KISS" (keep it simple) principle.	√
Users need to be taught how the system works.	√
Users must be allowed to purchase only what is appropriate for their use.	tbd
Any intervention imposed must be the least restrictive intervention.	√
The use of existing skills and the development of new skills must be encouraged.	√
Any stigmatising effects of the device or imposed practice must be considered.	√
Sharing new ideas and good practices will stimulate synergies and create economies in efforts (avoidance of duplication).	√

[23] http://seniorproject.eu/

4 Ethical Implications for LLM Pilot Conduct

4.1 About the LLM Pilots

The LLM service will be validated and tested for use by the implementation of pilot studies to be performed in five EU member countries: Austria, France, Greece, Spain and Cyprus. The pilots will be held over a period of 12 months, in 3 iterations of 3 months each, with one month in between for adaptation.

Each pilot partner is responsible for managing the pilot conduct in a manner that ensures a consistent approach to produce quality data about the performance of LLM. Each pilot site has defined the details of the pilot programme as it will be conducted at their location, in compliance with national regulatory requirements. These details are described in D4.1 "Pilot Deployment Plan."

The planned pilots are designed to address three different components of the LLM service, covering the whole value chain of interested parties. These are:

1. "At Home" installations: which directly refer to the end-users (the elders), by installing the solution in their home environment.
2. "Day-care centre" installations, where the LLM service will be installed in the corresponding facilities.
3. "Formal care facilities" (specialised hospitals, nursing homes for the elder, etc), who will install the solution in their facilities.

4.2 Ethical Guidelines for the LLM Pilot Study

According to the legal and ethical rights established in the directives discussed in detail in the LLM deliverable D6.1: Report on National & European Legislation, there are specific procedures that must be followed to protect the pilot participants. In addition, the ethical issues introduced in Section 1 must also be addressed.

Also note that several ethical issues that impact the LLM pilot study are discussed in deliverable D.6.2 Technical Specifications for User Privacy Reassurance. Specifically, the procedures for Informed Consent and Data Collection are provided in that document.

This Section discusses the ethical guidelines that will be followed before, during and after the LLM pilot studies to ensure that the highest standards are met throughout the entire lifecycle of the project.

4.2.1 Pre-Pilot Guidelines

Hiring of LLM Pilot Study Staff

- The LLM pilot partners ensure that the research staff has the necessary professional expertise and support required to run the study.

Assigning an Ethical Reviewer to Each Pilot Site

- If required by the Ethical Control Board in each pilot country, a local Ethics Review staff person may be assigned and trained to monitor the LLM pilot study to guarantee that all relevant procedures are strictly followed and that all local Ethics Committee recommendations and national relevant laws and directives are respected. In this case, the reviewers should also ensure that no undue risk for the elderly users, under any circumstances, is possible. Categories of risk include, but are limited to:
    - physical damage
    - psychological consequences
    - social consequences
    - privacy and confidentiality risks

*The LLM pilot partners that were required by country regulations to assign an ethical reviewer to their pilot study were AUTH (Greece), NKUA (Greece), and UCY (Cyprus). Any associated documentation will be kept on file at the pilot study site.

Recruiting and Screening Subjects

- No project staff should pressure, coerce or deceive respondents in an effort to ensure their participation. Staff should also try to ensure that respondents are not pressured by other family or community members.
- Staff should not make any promises they cannot or are unlikely to keep regarding the LLM pilot study. Nor should any recruitment materials or brochures provide deceptive or over-promising information to induce subjects to join the project.
- The respondents will have at least 24 hours to consider whether they want to take part and will be free to withdraw from the study at any time, without being required to give any reason.
- Staff will make every effort to make sure the participants understand the study and feel free not to take part or to withdraw if they wish to.
- Participants should be selected with respect for all groups in society, regardless of race, ethnicity, religion and culture.

Consent Forms and Voluntary Participation

The right to consent and voluntary participation in research is derived directly from the Nuremberg Code (1947)[24]:

> "The voluntary consent of the human subject is absolutely essential. This means that the person involved should have legal capacity to give consent; should be so situated as to be able to exercise free power of choice, without the intervention of any element of force, fraud, deceit, duress, overreaching, or other ulterior form of constraint or coercion; and should have sufficient knowledge and comprehension of the elements of the subject matter involved as to enable him to make an understanding and enlightened decision."

Before the pilot study commences, the informed consent *process* must be established. The pilot study staff must be aware of the following:

[24] http://ohsr.od.nih.gov/guidelines/nuremberg.html

- Be able to explain the consent form to prospective participants in such a way as to ensure the participant is made aware of all aspects of the study and gives their consent freely and without coercion. Explain how the data will be collected, stored, and used for the study. Who will supervise the data? How it will be expunged at the end of the study? Explain how the participant can leave the study, if so desired.
- Know how the consent forms will be collected and stored.

Informed consent procedures ensure that pilot participant are fully aware of the procedures, benefits and potential risks that may be involved from participating in the LLM pilot study. The Consent Form to be signed by all study participants will include the following:

- Every pilot participant must give his explicit consent to their participation and to the processing of their personal data.
- The Consent Form will clearly state the following:
    - The purpose and benefits of the research
    - All possible risks, discomforts, adverse side-effects, if any, resulting from participating in the study
    - Explanations of confidentiality – personal and data
    - Who to contact in case the participant chooses to withdraw from the study, and any consequences that may result from withdrawing
    - Who to contact for questions about the research
- Best practices will be employed in ensuring that participants will be fully informed of any implications, and are able to provide consent. These best practices will include the development of informed consent and release documents for signature by the end-user, in line with each country's relevant laws and regulations, and will accommodate the need to take special precautions for informed consent with end-users who may suffer from dementia or mild cognitive decline, and whose ability to provide consent may be in question. Such precautions would follow the approach used in medical clinical trials where the end-user's caregiver network and particularly, their primary caregiver, may be consulted in the informed consent process.

Determine How Data Will Be Handled

- In addition to Informed Consent for participation in the trial, each country will collect data transmission consent from the participants to permit the following:
    - the collection of personal health data
    - the anonymisation of that data
    - the transmission of that data for aggregation to a central server in Greece, and
- Determine which data are essential to the project and which data will be excluded from retention.

4.2.2 Pilot Guidelines

Ethical Treatment of Human Subjects

- As a standard across all pilot locations, the principles of Good Clinical Practice (GCP) will be used to ensure that protections will be taken to ensure the safety and protection of pilot study subjects.
- No privacy or human rights violations will injure the dignity of the participant in any way.

- LLM research participants will be protected from undue intrusion, distress, physical discomfort, personal embarrassment, or psychological or other harm at all times.
- Any psychological consequences will be carefully examined and monitored.
- All participants will be allowed freedom of choice regarding their participation in the pilot. His or her ability to make choices will never be in doubt or felt to be unattainable.

Security, Privacy and Data Protection

The responsible management of sensitive personal data is more than an undisputed objective; it constitutes an imperative obligation of any ICT solution that deals with the mental, physical and overall health condition of users. This need has been acknowledged by the LLM consortium, resulting in this publicly documented ethical guidelines report that will affect the technical and operational specifications of the pilot study and the LLM final solution design.

The flow of personal, health and training performance data across country borders for the purposes of the LLM pilot conduct is the single most critical issue to be addressed to ensure user privacy is properly and fully protected. To this end, the LLM project pilot studies will implement the following safeguards to personal data protection:

- In each country where the LLM pilot will be conducted, the project will be submitted to appropriate ethical review boards and data protection agencies for review, if required by country regulation.
- All collected data processed for statistical and/or scientific purposes shall be anonymous. One of the key aspects of ensuring data quality and subject protection under Good Clinical Practice (GCP) is to anonymise all the data associated with the subject throughout the course of the study. To this end, during the initial screening, each potential subject will be provided a study enrolment number, and all details of data, from demographic elements such as age and gender, to specific results of screening tests or outcome measure tests are tied only to this study enrolment number. A Subject Identification Code List will remain in the permanent files, only available at the pilot study site, with the names and addresses of the subjects to enable subjects to be contacted, e.g., if there were some need to communicate pertinent health-related data to them subsequent to their participation in the study.
- Tests that are performed for screening or measuring health conditions for a subject will be documented in physical files which are kept only at the pilot study location, and are not provided in their totality to any other organisation, except as required by law. Summarised scores of tests will be provided as input to the LLM system in order to identify health benefits (if any) resulting from the LLM intervention.
- Any physical files containing detailed testing results for the subject, identified only by enrolment number, will be kept at each pilot study site.
- Where the data are contained in lists, registers, and/or electronic databases, they shall be processed by using either encryption techniques or identification codes and/or other solutions that make said data temporarily unintelligible also to those entities that are authorised to access them and allow identifying data subjects only if this is necessary.
- All data will be protected and handled according to the corresponding National Laws of the countries where the pilots will be run, as discussed in detail in LLM deliverable D6.1: Report on National and European Legislation.

- Personal data shall be processed fairly and lawfully.
- Personal data shall be obtained only for one or more specified and lawful purposes, and shall not be further processed in any manner incompatible with that purpose or those purposes.
- Personal data shall be adequate, relevant and not excessive in relation to the purpose or purposes for which they are processed.
- Personal data shall be accurate and, where necessary, kept up to date.
- All subjects have the right to their data, upon written request, during the pilot study.
- Personal performance data will remain locally stored and encrypted at each LLM installation.
- Emergency notifications will only be published to the relatives or caretakers of the elders; as such, pieces of information may never be disclosed to third-parties.
- Personal data shall be processed in accordance with the rights of data subjects.
- Appropriate technical and organisational measures shall be taken against unauthorised or unlawful processing of personal data and against accidental loss or destruction of, or damage to, personal data.
- All personal data being transferred out of the country in which it was collected and to the central LLM database server in Greece will be subject to an adequate level of protection for the rights and freedoms of data subjects.
- All persons in charge of collecting data shall disclose their identities and functions and the purposes of data collection by means of appropriate documents.
- The collection and monitoring of behavioural data about the elderly participants will be retained as raw data locally in the HCU (Home Control Unit), and will trigger an alarm/signal to an external third party for attention under exception conditions only, without providing any detailed personal or location data.

4.2.3 Post-Pilot Guidelines

- All subjects have the right to their data upon written request up to 12 months after the pilot study has ended.
- All collected personal data will be destructed no earlier than 12 months after the pilot study has ended, or after the period required by the pilot country's regulations.
- Personal data processed for any purpose or purposes shall not be kept for longer than is necessary for that purpose or those purposes.
- LLM partners will ensure that methodology and findings are open for discussion and peer review after the pilot study has ended.
- For purposes of scientific analysis, the results of the LLM pilot studies for all subjects will be aggregated, although some study results are expected to be identified by country, in case some differences exist in the availability of data for some outcome measures. However, none of these data will be identifiable with any single individual at any time.

5 Ethical Implications for LLM Product Solution Design

While the importance of maintaining ethical standards will continue to apply in the LLM production environment, the ethical issues may vary slightly from those outlined for the LLM pilot study. Differences arise due to the fact that the use of the actual LLM service will be more "interest based." In other words, users will have either directly purchased the LLM solution for use in their home, or they will be using the LLM service under the care and guidance of a caregiver organization. At home, consent forms are obviously unnecessary. And in the later case, any required consents or approvals will fall under the dictate of the organization implementing the LLM system.

Regardless of consent and where LLM will be used, there are still ethical standards to which the LLM service must adhere. As outlined in the earlier section of this document pertaining to the LLM pilot study, the LLM user must always remain free from harm, and privacy, confidentiality and security concerns must be addressed. However, there are additional ethical issues that must be taken into consideration for the marketed LLM product.

Further, the marketed LLM service must adhere to e-inclusion and good practice strategies, as outlined earlier in this document.

5.1 Security Issues

The LLM solution will handle sensitive information that must be protected.

- **Authentication** – The LLM system must be able to determine whether the user is who they declare to be. This is a fundamental security requirement and preserves the integrity of the LLM system. Authentication will be accomplished through the use of individual User IDs.
- **Authorization** – The LLM system must be able to distinguish between different types of users to control what information, applications, and services the user can access. LLM will have three types of users – the elderly user, the caregiver, and the administrator. Authorization is generally accomplished through the definition of appropriate permissions in a user's account.
- **Administration** - The ethical responsibility of processing, protecting and ensuring the confidentiality of personal data falls to all LLM staff members who have access to any collected personal data. It must be guaranteed that all appropriate measures must be implemented to protect this personal data against accidental or unlawful destruction or accidental loss, alteration, unauthorised disclosure or access.
- **Physical security safeguards** – Standard security safeguards will be included in the LLM project, including:
  - Wireless access points shall be located in secured rooms, accessible only to authorized personnel.
  - Physical access to the LLM system LUI will be controlled by the location of the system in a secured room, accessible only to authorized personnel, including pilot subjects.
  - All physical files shall be kept in locked, fire-proof cabinets at the pilot site only, or at a separate office location or off-site storage facility (e.g., after the

conclusion of the pilot study), and will be accessible only by authorized staff who are trained in pilot procedures, including the proper handling of subject data.
- Individually identifiable data, including the Subject Identification Code List, signed Informed Consent Forms, etc. will be kept separately from files with testing logs, screening test, or outcome measure results.

Additional issues related to data security are discussed below under section 5.3. Privacy and Data Protection Issues.

5.2 Personal and Societal Issues

- **Accessibility** – The LLM system must adopt a design-for-all approach. The devices and interfaces must be user-friendly and serve the needs and requirements of the elderly. The system must also comply with any accessibility standards imposed on the assistive technology products market.
- **Isolation** – The LLM system must NOT foster isolation of the elderly user. While the system may be used in the elderly person's home, the consequence of doing so must not have any negative effects on the user's social ties or potential for communication.
- **Discrimination** – The LLM system must not discriminate amongst potential users and users of the system.
- **Beneficence** – The LLM system must contribute to the user's welfare, and complementary with other devices, strive to improve the quality of life.

5.3 Privacy and Data Protection Issues

All of the privacy and data directives previously discussed in this document and in LLM deliverable D6.1: Report on National & European Legislation will be strictly adhered to. In addition, the following specific issues will be addressed in the marketed LLM service:

- Data integrity - Data Integrity assures that information stored on a system is reliable and can be trusted. Important factors of this measurement are: consistency, accuracy, and correctness of data stored in a database.
- Procedures for data collection, transmission, storage, and anonymisation must be clearly established and adhered to.
- In a production setting, it is expected that at least one server will be established within a country to support users effectively. Therefore, a user's personal health data will not be transmitted out of the country.
- The system will be designed in a manner that recognises that data collected about an individual's activity in the home is their own data and that wherever data must be transmitted outside the home environment over a network, that protections are used, including, but not limited to data encryption.
- The system will be designed in a manner that minimises the intrusiveness of the technological components.
- The technological components will be configured in ways that promote user control as much as possible.
- Privacy of the person and person's behaviour must be protected. Sensitive matters and preferences will not be collected in any fashion.

6 Annex: Supporting Documents

Copies of the following documents are included in this Annex:

- LLM Participant Information Sheet
- LLM Informed Consent Form

**Any additional consent and approval forms as required by pilot country regulations (e.g., Data Transmission Consent Forms, Ethics Committee Approvals) will remain on file with the respective pilot study partners.

6.1 LLM Participant Information Sheet

Long Lasting Memories (LLM) is a project funded by the European Commission, and is being conducted in 5 EU countries. The project includes a programme that is designed for adults over the age of 65, and which combines physical activity and cognitive exercises together to determine the effects on health. During the programme, we will collect data, which will be stored in an anonymous form, about the cognitive and physical health of each participant at the beginning and ending of the programme. This information will be used solely for scientific and technical research purposes.

Who can participate?	Adults over the age of 65 who wish to volunteer, and who are healthy enough to participate. Our therapists will work with each individual to determine if there are any reasons they should not be included in the test programme.
What is the cost of the programme?	There is no cost to participate in the programme, and volunteers will not receive any payments for participating.
What is the level of commitment a participant needs to make?	The programme will be conducted for a period of 8 weeks, and each participant will do specific physical activities or cognitive exercises (on a touch screen computer) for 1 hour sessions 5 times per week. Before and after the programme you will be tested with a series of cognitive and physical fitness tests that are designed to track the success of the programme. Additionally, there will be a follow-up test 3 months post after you finished the programme.
Do I need to know anything about computers to participate?	No. Although computers are used in the programme, there is no need for you to know anything about them, and the training to do the programme is very simple and easy.
What are the risks?	Both the physical activity and the cognitive exercises will be adapted to the individual, and will be designed in a manner that should not create any health risks to the individual. However, before participating, each person will be asked to confirm with his or her primary physician that it will be safe for them to join.

What sorts of physical activities are involved?	The activities may include the use of treadmills, recumbent bicycles, and the Wii™ system, along with activities guided by an instructor. The specific details of the activities will depend upon the individual's current state of health, and may be adapted during the course of the programme.
Can I get access to the information gathered about me during the programme?	Yes. While details about each individual's health will be stored in an anonymous form on computer systems, each person has the right to review any of this information at any time during or after the conclusion of the programme.
Can I drop out of the programme?	Yes. You have the right to end your participation in the programme at any time. You do not have to give a reason, and there will be no consequences to you should you decide not to complete the programme.

6.2 LLM Informed Consent Form

Enrollment Number:

Consent to Participate

Long Lasting Memories is a project which combines a programme of physical activity with cognitive exercises performed on a touch-screen computer. This project will measure the effects, if any, of this combination as a way to counteract age-related cognitive decline and the impact on general measures of physical fitness.

The project will be held at the following location: _____

The duration of the project will be *x* weeks, beginning on _____ and ending on _____, and project participants will attend sessions lasting *x hours* each day, *x* times per week. The duration and the difficulty level of both the cognitive and physical training will be adapted to each individual, in order not to cause any discomfort and to avoid risks.

Any findings or diagnoses during the project will be revealed to the participant confidentially. Well trained therapists will be supervising the trials and the progress of each participant individually. They will also be at the participants' disposal to address any questions or complaints.

The personal data of the participants will be safely stored and will be available only to the local project staff until the completion of the project. The results of the research will be published only in aggregate terms, and all data will be made anonymous for scientific study and as published in confidential and public reports. The following are contact details for the National Data Protection Supervisor, to which any concerns about data protection may be made known: *(insert name and contact details here).*

The project will be conducted in compliance with the *(insert appropriate regulatory references here).*

Participation is voluntary and participants are free to withdraw at any time without providing any reason, and without any consequences.

INFORMED CONSENT

I, the undersigned, _____, voluntarily agree to participate in the activities of the Long Lasting Memories project as described above and in the accompanying informational document.

Signature of Subject	Date
Subject name (printed)	
Signature of Researcher	Date