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D6.1 Report on National & European Legislation

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Abstract

This deliverable provides all the participants in the LLM Project with background on the legal framework applicable to the development of the LLM solution, as well as to the ethical conduct of the pilot of LLM (which includes human subjects) within a European context. This report examines legislation, directives, and other notable published guidances on a European and international level which may serve as directly applicable, or as advisory in nature.

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Executive Summary

The purpose of this Report on National & European Legislation is to provide all the participants in the LLM Project with background on the legal framework applicable to the development of the LLM solution, as well as to the ethical conduct of the pilot of LLM (which includes human subjects) within a European context. This report examines legislation, directives, and other notable published guidances on a European and international level which may serve as directly applicable, or as advisory in nature. In addition, for each of the countries where LLM will be piloted, a detailed description of the national regulations for conducting the pilot is included.

European and international legislation is presented first, followed by a Section for each of the countries represented in the LLM consortium, including:

- Austria
- France
- Germany
- Greece
- Spain
- UK
- Cyprus

Note that while the LLM pilot will not be conducted in Germany or the UK, the consortium is represented in those countries, and thus, only non-pilot related legislation (i.e., that may impact the design of the LLM solution) is examined in this document.

In many cases this document includes the text of specific relevant legislation or directives, or in the case of countries where a language other than English is used, an English language summary or interpretation is provided. At the end of each Section, there is a summary table listing the relevant legislation/regulatory documents or directives as well as specific organisations involved in establishing standards or regulating compliance with ethical and legal standards on a European or national level.

Please note that although this document includes references and information pertaining to "clinical studies," the LLM project 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 in this document 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.

Table of Contents

1 EUROPEAN LEGISLATION/DIRECTIVES

1.1 Legal Basis for Ethical Reviews

To protect the fundamental rights and freedoms of persons involved in publicly funded research, the European Parliament and the Council have put certain legal directives in place regarding the review of ethical issues stemming from research activities supported by the European Commission's 7th Framework Programme. The directives make it compulsory to carry out ethical reviews and require that experiments or research where humans are used be subject to authorization and review. All consortia involved in research funded by the European Commission must take into account the legislation, regulations, ethical rules and/or codes of conduct in place in the country(ies) where the research is to take place.

For the LLM project, the project consortium is responsible for investigating the ethical and legal issues as they relate to conclusions and decisions on the approaches to be followed during the technical integration of the system and the rules to adhere to while offering improved care through the use of ICT. The ethical and legal directives outlined in this document will be adhered to for the duration of the LLM pilot studies as well as to the ultimate commercialization of the LLM product.

Based upon this detailed review, all relevant national and European level requirements will be advised, considered and applied throughout the LLM project development process. Because the LLM project consists of partners from several European countries, developing an ICT solution involving humans, the national legislation of each individual consortium partner country involved will also be considered, ultimately enabling the LLM solution to be delivered competitively across the EU.

> Ethical and legal reviews ensure citizens and decision-makers that the publicly funded research complies with the highest standards and makes certain that there has been full consideration of all issues in an attempt to eliminate any harm to which research subjects may be exposed.

The legal basis for ethical reviews considered for the LLM project is obtained from the following, which includes directives and legally enforceable instruments at a European level:

1) Charter of Fundamental Rights of the European Union
2) The European Human Rights Convention
3) European Commission's Seventh Framework Programme (2007-2013)

- **Charter of Fundamental Rights of the European Union**[1]
  The European Union Charter of Fundamental Rights defines all civil, political, economic and social rights of European citizens and all persons resident in the European Union. The principles covered include dignity, freedoms, equality, solidarity, citizens' rights and justice, and are reviewed in further detail in the following Section of this Report.

- **The European Human Rights Convention**[2]
  This document was the first major treaty of the Council of Europe, and outlines basic human rights, liberties and freedoms for the citizens of European countries.

  The following Articles in the European Human Rights Convention will inform the LLM pilot studies and development process:

  Section I: Rights and freedoms

  Article 8: Right to respect for private and family life

  1. Everyone has the right to respect for his private and family life, his home and his correspondence.
  2. There shall be no interference by a public authority with the exercise of this right except such as is in accordance with the law and is necessary in a democratic society in the interests of national security, public safety or the economic well-being of the country, for the prevention of disorder or crime, for the protection of health or morals, or for the protection of the rights and freedoms of others.

- **European Commission's Seventh Framework Programme (2007-2013)**[3]
  This directive concerns the Seventh Framework Programme of the European Community for research, technological development and demonstration activities. The following items and Articles will inform the LLM pilot studies and development process:

  (23) Participation in the activities of the Seventh Framework Programme should be facilitated through the publication of all relevant information, to be made available in a timely and user-friendly manner to all potential participants and the appropriate use of simple and quick procedures, free of unduly complex financial conditions and unnecessary reporting, in accordance with the Rules for Participation applicable to this Framework Programme, laid down in Regulation (EC) No 1906/2006 of the European Parliament and of the Council of 18 December 2006 laying down the rules for the participation of undertakings, research centres and universities in actions under the Seventh Framework Programme and for the dissemination of research results (2007-2013).

[1] 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
[2] 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
[3] 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

(30) Research activities supported by the Seventh Framework Programme should respect fundamental ethical principles, including those reflected in the Charter of Fundamental Rights of the European Union. The opinions of the European Group on Ethics in Science and New Technologies are and will be taken into account. Research activities should also take into account the Protocol on the Protection and Welfare of Animals and reduce the use of animals in research and testing, with a view ultimately to replacing animal use.

Article 6: Ethical principles:

1. All the research activities carried out under the Seventh Framework Programme shall be carried out in compliance with fundamental ethical principles.

In addition to these articles, the **Annex** to the FP7 ICT Research Guide for Applicants (Annex 5 - Ethical Guidelines for Undertaking ICT Research in FP7[4]) provides further guidance to researchers in identifying ethical issues that might arise from their ICT research.

The Annex includes guidelines for a responsible approach to research and privacy, as well as informed consent. The following guidelines will inform the LLM pilot studies and development process:

2. Conduct of ICT Research

2.2 Privacy and informed consent

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

Researchers must be aware that volunteers have the right to remain anonymous. Researchers must comply with Data Protection legislation in the Member State where the research will be carried out regarding ICT research data that relates to volunteers.

Informed consent is required whenever ICT research involves volunteers in interviews, behavioural observation, invasive and non-invasive experimentation, and accessing personal data records. The purpose of informed consent is to empower the individual to make a voluntary informed decision about whether or not to participate in the research based on knowledge of the purpose, procedures and outcomes of the research.

Before consent is sought, information must be given specifying the alternatives, risks, and benefits for those involved in a way they understand. When such information has been given, free and informed consent must be obtained. Depending on the nature of the research, different consent

[4] ftp://ftp.cordis.europa.eu/pub/fp7/docs/guidelines-annex5ict.pdf

procedures may be used. Special consideration must be given when volunteers have reduced autonomy or are vulnerable.

The majority of European citizens view personal privacy as an important issue. Research, for example, on RFID and ICT for healthcare, is likely to raise privacy issues. Therefore, researchers must ensure that the manner in which research outcomes are reported does not contravene the right to privacy and data protection. Furthermore, researchers must carefully evaluate and report the personal privacy implications of the intended use or potential use of the research outcomes. Wherever possible, they must ensure that research outcomes do not contravene these fundamental rights.

3. Specific guidance in some sensitive areas

3.1 ICT implants and wearable computing

- ICT implants should only be developed if the objective cannot be achieved by less-invasive methods such as wearable computing devices and RFID tags.
- To the extent that an individual, via an ICT implant or wearable computing device, becomes part of an ICT network, the operation of this whole network will need to respect privacy and data protection requirements.
- ICT implants in healthcare are, in general, acceptable when the objective is saving lives, restoring health, or improving the quality of life. They should be treated in the same way as drugs and medical devices.[5]
- ICT implants to enhance human capabilities should only be developed: to bring individuals into the "normal" range for the population, if they so wish and give their informed consent; or to improve health prospects such as enhancing the immune system. Their use should be based on need, rather than economic resources or social position.
- ICT implants or wearable computing devices must not: allow individuals to be located on a permanent and/or occasional basis, without the individual's prior knowledge and consent; allow information to be changed remotely without the individual's prior knowledge and consent; be used to support any kind of discrimination; be used to manipulate mental functions or change personal identity, memory, self-perception, perception of others; be used to enhance capabilities in order to dominate others, or enable remote control over the will of other people.
- ICT implants should not be developed to influence future generations, either biologically or culturally.
- ICT implants should be developed to be removed easily.

[5] Such research is partly covered by Council Directive 90/385/EEC relating to active implantable medical devices. http://europa.eu.int/eurlex/en/consleg/pdf/1990/en_1990L0385_do_001.pdf

3.2 eHealth and genetics

Personal health data must be treated as 'sensitive personal data'. ICT researchers using it have a duty of confidentiality equivalent to the professional duty of medical secrecy. Therefore:

- The use of personal health data in ICT research for the purposes from which society as a whole benefits must be justified in the context of the personal rights.
- The security of ICT in healthcare is an ethical imperative to ensure the respect for human rights and freedoms of the individual, in particular the confidentiality of data and the reliability of ICT systems used in medical care.
- Proposers should be particularly aware when ICT is linked to sensitive medical areas such as the use of genetic material.
- Proposers should access established general medical and genetics ethical guidance when formulating their proposals.

1.2 European Charter of Fundamental Rights and International Conventions

The LLM individual consortium partners will fully comply with all European Union legislation regarding research concerning elderly users of the LLM system. The EU legislation to which the LLM project will adhere includes the directives listed below:

Charter of Fundamental Rights of the European Union [6]

It is likely that most of the principles of the Charter of Fundamental Rights of the European Union will be relevant to the approach adopted by the LLM consortium; however, in particular, the following Articles will inform the LLM pilot studies and development process:

Chapter I: Dignity

Article 1: Human dignity

Human dignity is inviolable. It must be respected and protected.

Article 3: Right to the integrity of the person

1. Everyone has the right to respect for his or her physical and mental integrity.
2. In the fields of medicine and biology, the following must be respected in particular:
   - the free and informed consent of the person concerned, according to the procedures laid down by law,
   - the prohibition of eugenic practices, in particular those aiming at the selection of persons,
   - the prohibition on making the human body and its parts as such a source of financial gain,
   - the prohibition of the reproductive cloning of human beings.

[6] 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

Chapter II: Freedoms

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

1. Everyone has the right to the protection of personal data concerning him or her.
2. 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.
3. Compliance with these rules shall be subject to control by an independent authority.

Directive 95/46/EC of the European Parliament and of the Council[7]

This directive contains a number of key principles that must be complied with pertaining to the protection of individuals with regard to the processing of personal data and the free movement of such data. Anyone processing personal data must comply with the enforceable principles included in this directive.

The articles in Directive 95/46/EC state that any personal data collected and/or processed must be:

- Fairly and lawfully processed.
- Processed for limited purposes.
- Adequate, relevant and not excessive.
- Accurate.
- Not kept longer than necessary.
- Processed in accordance with the data subject's rights.
- Secure.
- Not transferred to countries without adequate protection.

World Medical Association Declaration of Helsinki[8]

This document is a statement of ethical principles for medical research involving human subjects, including research on identifiable human material and data. The fundamental principles in this document concern the following:

- respect for the individual by upholding ethical standards (Article 9)
- right to informed consent (Articles 22, 24, 25, 26, 27, 28)
- right to privacy protection (Article 23)
- the investigator's duty is solely to the patient (Articles 3, 4, 6, and 11)

[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] World Medical Association Declaration of Helsinki , 59th WMA General Assembly, Seoul, October 2008. http://www.wma.net/en/30publications/10policies/b3/index.html

- the subject's welfare must always take precedence over the interests of science and society (Article 6)
- ethical standards must always be upheld (Article 9 and 10)
- studies must follow protocols and get approval from an ethics committee (Articles 15 and 16)

Specifically, paragraph B13 states:

> *"The design and performance of each experimental procedure involving human subjects should be clearly formulated in an experimental protocol. This protocol should be submitted for consideration, comment, guidance, and where appropriate, approval to a specially appointed ethical review committee, which must be independent of the investigator, the sponsor or any other kind of undue influence. This independent committee should be in conformity with the laws and regulations of the country in which the research experiment is performed. The committee has the right to monitor ongoing trials. The researcher has the obligation to provide monitoring information to the committee, especially any serious adverse events. The researcher should also submit to the committee, for review, information regarding funding, sponsors, institutional affiliations, other potential conflicts of interest and incentives for subjects."*

Convention for the Protection of Individuals with regard to Automatic Processing of Personal Data (ETS No. 108)[9]

The Convention for the Protection of Individuals with regard to Automatic Processing of Personal Data (ETS No. 108) was drawn up under the authority of the European Committee on Legal Co-operation (CDCJ) in Strasbourg, France (1981) and served to strengthen the protection of individuals with regard to the automatic processing of personal data in the public and private sectors. This Convention was signed at a time when most data was processed manually, but the potential for automatic "intelligent" data processing was soon expected.

The objective of the Convention is stated in Article 1 as follows:

> "to secure in the territory of each Party for every individual, whatever his nationality or residence, respect for his rights and fundamental freedoms, and in particular his right to privacy, with regard to automatic processing of personal data relating to him ("data protection")."

The Convention is also important due to the fact that it has provided for accession by non-member States, according to Article 23(1), as follows:

> "After the entry into force of this convention, the Committee of Ministers of the Council of Europe may invite any State not a member of the Council of Europe to accede to this convention by a decision taken by the majority provided for in Article 20.d

[9] http://www.litbang.depkes.go.id/ethics/knepk/kegiatan/basic/declarat/datprotcon.htm

of the Statute of the Council of Europe and by the unanimous vote of the representatives of the Contracting States entitled to sit on the committee."

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)[10]

This international treaty signed on 4 April 1997 in Oviedo, Spain is also known as "The European Convention on Human Rights and Biomedicine." Developed by The Council of Europe, the Convention contains principles and requirements that govern research using human subjects and has become national law in the countries that have ratified it.

Among the fundamental principles in the Convention to which the LLM project will adhere are the following:

Chapter I – General provisions

Article 1 – Purpose and object
Parties to this Convention shall protect the dignity and identity of all human beings and guarantee everyone, without discrimination, respect for their integrity and other rights and fundamental freedoms with regard to the application of biology and medicine.

Each Party shall take in its internal law the necessary measures to give effect to the provisions of this Convention.

Article 2 – Primacy of the human being
The interests and welfare of the human being shall prevail over the sole interest of society or science.

Article 3 – Equitable access to health care
Parties, taking into account health needs and available resources, shall take appropriate measures with a view to providing, within their jurisdiction, equitable access to health care of appropriate quality.

Article 4 – Professional standards
Any intervention in the health field, including research, must be carried out in accordance with relevant professional obligations and standards.

Chapter II – Consent

[10] http://shr.aaas.org/article15/Reference_Materials/CoE_Conv_on_HRs_and_Biomedicine_Eng.pdf

Article 5 – General rule
An intervention in the health field may only be carried out after the person concerned has given free and informed consent to it.

This 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.

Chapter III – Private life and right to information

Article 10 – Private life and right to information
1 Everyone has the right to respect for private life in relation to information about his or her health.
2 Everyone is entitled to know any information collected about his or her health. However, the wishes of individuals not to be so informed shall be observed.

1.3 Community Regulations (EC)

1.3.1 Clinical trials

Please note that the LLM project trials are not clinical trials. All clinical trial regulation and legislation references in this document have been included only to maintain the highest level of integrity of the study and to ensure that we stay as close to those standards as is possible.

The basic principles for the conduct of clinical trials in humans are based on the protection of human rights and human dignity as defined by the principles established by the following directives and organizations:

Clinical Trial Directive 2001/20/EC[11] and Good Clinical Practice
In response to a growing concern among regulators and the public regarding how clinical trials are conducted from an ethical and legal standpoint, the European Commission issued Directive 2001/20/EC, which provides guidances on the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use. The directive is clear on matters affecting subjects in clinical trials, in particular informed consent and the protection of subjects.

Although the directive focuses on clinical trials regarding medicinal products, many of the guidances can be applied to any type of clinical trial being conducted in the Member States, for example:

[11] Official Journal of the European Communities, Directive 2001/20/EC, 4 April 2001. http://www.wctn.org.uk/downloads/EU_Directive/Directive.pdf

- (2) The accepted basis for the conduct of clinical trials in humans is founded in the protection of human rights and the dignity of the human being with regard to the application of biology and medicine, as for instance reflected in the 1996 version of the Helsinki Declaration.

- (3) Persons who are incapable of giving legal consent to clinical trials should be given special protection. It is incumbent on the Member States to lay down rules to this effect. Such persons may not be included in clinical trials if the same results can be obtained using persons capable of giving consent.

- (4) In the case of other persons incapable of giving their consent, such as persons with dementia, psychiatric patients, etc., inclusion in clinical trials in such cases should be on an even more restrictive basis.

- (9) Information on the content, commencement and termination of a clinical trial should be available to the Member States where the trial takes place and all the other Member States should have access to the same information. A European database bringing together this information should therefore be set up, with due regard for the rules of confidentiality.

- (15) The verification of compliance with the standards of good clinical practice and the need to subject data, information and documents to inspection in order to confirm that they have been properly generated, recorded and reported are essential in order to justify the involvement of human subjects in clinical trials.

- (16) The person participating in a trial must consent to the scrutiny of personal information during inspection by competent authorities and properly authorised persons, provided that such personal information is treated as strictly confidential and is not made publicly available.

In addition, the following Articles in Directive 2001/20/EC contain guidances that will be used in the LLM trials:

- Article 1: Scope
- Article 2: Definitions
- Article 3: Protection of clinical trial subjects
- Article 6: Ethics committee
- Article 9: Commencement of a clinical trial
- Article 10: Conduct of a clinical trial
- Article 11: Exchange of information
- Article 15: Verification of compliance of investigational medicinal products with good clinical and manufacturing practice
- Article 16: Notification of adverse events
- Article 18: Guidance concerning reports

Directive 95/46/EC[12] and Data Protection / Participant Privacy
Refer to the preceding section where the impacts of the Privacy Directive (95/46/EC) are described in detail.

GCP CPMP/ICH135/95[13] (Annex to Directive 75/318/EEC as amended) and Informed Consent
This Directive thoroughly discusses the guidelines that should be followed when generating clinical trial data that are intended to be submitted to regulatory authorities.

The Directive defines Good Clinical Practice (GCP) as:

> "… an international ethical and scientific quality standard for designing, conducting, recording and reporting trials that involve the participation of human subjects. Compliance with this standard provides public assurance that the rights, safety and well-being of trial subjects are protected, consistent with the principles that have their origin in the Declaration of Helsinki, and that the clinical trial data are credible.
>
> The objective of this ICH GCP Guideline is to provide a unified standard for the European Union (EU), Japan and the United States to facilitate the mutual acceptance of clinical data by the regulatory authorities in these jurisdictions."

The contents of GCP CPMP/ICH135/95 that will be used to inform the LLM pilot trials include information regarding the principles of good clinical practice, the procedures involved in good clinical practice, informed consent of trial subjects, reporting, trial design and management, and clinical trial protocol.

The Directive also includes a detailed list of essential documents required for the conduct of a clinical trial.

World Medical Association Declaration of Helsinki
With respect to clinical trials research, this Declaration (discussed in detail in a prior Section) states the following:

- (19) Every clinical trial must be registered in a publicly accessible database before recruitment of the first subject.

[12] 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
[13] European Medicines Agency, Guideline for Good Clinical Practice. http://ec.europa.eu/enterprise/pharmaceuticals/eudralex/vol-10/3cc1aen.pdf

Clinical Trial Database Collection - EudraCT[14]

The European Union has also established a clinical trials database called EudraCT, which contains all information regarding the content, commencement and termination of all clinical trials in the European Union (from 1 May 2004 onwards). It was established in accordance with Directive 2001/20/EC, and is managed by the European Medicines Agency (EMEA).

1.3.2 Data protection

The responsible management of sensitive personal data is more than an undisputed objective of the LLM project; 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 and the undertaking of that obligation will be informed by the national and legislative data protection directives as discussed in this document, a thorough review of the European and Member States' legislation that should and will affect the technical and operational specifications of the LLM pilot studies and service.

The National Data Protection Commissioners throughout the European Union provide information, advice and guidance on data. Contact details for the data protection authorities of the Member States can be found on the European Commission website[15]. The National Data Protection Commissioners for the LLM consortium members and pilot-hosting countries are included in the corresponding sections of this document.

Legislative documents, main proposals and Community acts regarding data protection in Europe include the following:

Directive 95/46/EC[16]

The Data Protection Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 serves as the reference text for data protection issues throughout Europe. The guidances established in this Directive serve to protect the privacy of individuals in regards to the processing of their personal data and the movement of such data. The Directive sets strict limits on the collection and use of personal data and also requires that each Member State set up an independent national body responsible for the protection of these data.

The Directive focuses on several key principles concerning the use of and access to personal data with which all member states must comply. Any organisation processing or holding personal data must comply with the eight enforceable principles of good practice in Section 1, as follows:

[14] https://eudract.emea.europa.eu/index.html
[15] http://ec.europa.eu/justice_home/fsj/privacy/nationalcomm/index_en.htm
[16] 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

Article 6

1. Member States shall provide that personal data must be:
   (a) processed fairly and lawfully;
   (b) collected for specified, explicit and legitimate purposes and not further processed in a way incompatible with those purposes. Further processing of data for historical, statistical or scientific purposes shall not be considered as incompatible provided that Member States provide appropriate safeguards;
   (c) adequate, relevant and not excessive in relation to the purposes for which they are collected and/or further processed;
   (d) 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;
   (e) kept in a form which permits identification of data subjects for no 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.

The guidelines in this Directive pertain to the following topics:

- General Rules on the Lawfulness of the Processing of Personal Data
- Principles Relating to Data Quality
- Criteria for Making Data Processing Legitimate
- Special Categories of Processing
- Information to be Given to the Data Subject
- The Data Subject's Right of Access to Data
- Exemptions and Restrictions
- The Data Subject's Right to Object
- Confidentiality and Security of Processing
- Notification
- Judicial Remedies, Liability and Sanctions
- Transfer of Personal Data to Third Countries
- Codes of Conduct
- Supervisory Authority and Working Party on the Protection of Individuals with Regard to the Processing of Personal Data
- Community Implementing Measures

Directive 2000/C 364/01[17]

According to the Charter of Fundamental Rights of the European Union (2000/C 364/01), the protection of personal data is a fundamental right:

1. Everyone has the right to the protection of personal data concerning him or her.

[17] Official Journal of the European Communities, Charter of Fundamental Rights of the European Union (2000/C 364/01), Chapter II, Article 8, 18 Decmber 2000. http://www.europarl.europa.eu/charter/pdf/text_en.pdf

2. 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.
3. Compliance with these rules shall be subject to control by an independent authority.

Directive 2002/58/EC[18]

Directive 2002/58/EC of the European Parliament and of the Council of 12 July 2002 concerning the processing of personal data and the protection of privacy in the electronic communications sector (Directive on privacy and electronic communications). This Privacy Directive updated the Telecommunications Data Protection Directive (Directive 97/66/EC – see below) in the light of new technologies ensuring that the privacy rules which applied to phone and fax services also applied to e-mail and use of the Internet.

Directive 97/66/EC[19]

Directive 97/66/EC of the European Parliament and of the Council of 15 December 1997 concerns the processing of personal data and the protection of privacy in the telecommunications sector. This Directive was updated with Directive 2002/58/EC.

Directive 2006/24/EC[20]

Directive 2006/24/EC of the European Parliament and of the Council of 15 March 2006 on the retention of data generated or processed in connection with the provision of publicly available electronic communications services or of public communications networks and amending Directive 2002/58/EC.

This Directive pertains to data generated or processed as a consequence of a communication or a communication service.

Regulation (EC) 45/2001[21]

Regulation (EC) 45/2001 of the European Parliament and of the Council of 18. December 2000 on the protection of individuals with regard to the processing of personal data by the Community institutions and bodies and on the free movement of such data.

The persons to be protected in this Directive are those whose personal data are processed by Community institutions or bodies in any context whatsoever, for example because they are employed by those institutions or bodies.

[18] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2002:201:0037:0047:EN:PDF
[19] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:1998:024:0001:0008:EN:PDF
[20] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2006:105:0054:0063:EN:PDF
[21] http://ec.europa.eu/justice_home/fsj/privacy/docs/application/286_en.pdf

This Directive is based on two main principles:

1. The responsible data controller needs to respect a number of obligations. For instance, personal data can only be processed for a specific and legitimate reason which must be stated when the data are collected.
2. The person whose data are processed - the data subject - enjoys a number of enforceable rights. This includes, for instance, the right to be informed about the processing and the right to correct data.

In addition to the Directives from the European Commission regarding privacy and data protection, there are several bodies that have produced important documents. Among these are the following:

European Data Protection Supervisor (EDPS)[22]
According to the EDPS web site:

> "The EDPS is an independent supervisory authority devoted to protecting personal data and privacy and promoting good practice in the EU institutions and bodies. It does so by:
>
> - monitoring the EU administration's processing of personal data;
> - advising on policies and legislation that affect privacy; and
> - co-operating with similar authorities to ensure consistent data protection."

The EDPS was established by the European Parliament and Council to ensure that the EU institutions and bodies process personal data of EU staff and others lawfully. The EDPS oversees Regulation (EC) 45/2001 on data protection.

The EDPS states that every institution or body should have an internal Data Protection Officer who is responsible for keeping a register of processing operations and notifying systems with specific risks to the EDPS. Further, the EDPS works in cooperation with the Data Protection Authorities from Member States to promote consistent data protection throughout Europe. The Article 29 Data Protection Working Party (discussed below) is that platform which promotes uniform application of the general principles of the Directives in all Member States through the co-operation between Data Protection supervisory authorities.

Article 29 Data Protection Working Party[23]
The central platform for cooperation amongst all national data protection supervisory authorities is the Article 29 Working Party which was established by Article 29 of Directive 95/46/EC**.** All data protection authorities from the Member States work under the Article 29 Data Protection Working Party with a representative from the European Commission to consider and provide opinions on various data protection issues, including the provision of advice.

[22] http://www.edps.europa.eu/EDPSWEB/edps/lang/en/pid/1
[23] http://ec.europa.eu/justice_home/fsj/privacy/workinggroup/index_en.htm

The Working Party was set up to achieve several primary objectives[24]:

- To provide expert opinion from member state level to the Commission on questions of data protection.
- To promote the uniform application of the general principles of the Directives in all Member States through co-operation between data protection supervisory authorities.
- To advise the Commission on any Community measures affecting the rights and freedoms of natural persons with regard to the processing of personal data and privacy.
- To make recommendations to the public at large, and in particular to Community institutions on matters relating to the protection of persons with regard to the processing of personal data and privacy in the European Community.

The Article 29 Working Party has also created several documents and rulings[25] pertaining to data protection that may apply to the LLM project. For example:

- Article 29 Data Protection Working Party, Opinion on the use of location data with a view to providing value-added services, 2130/05/EN, WP 115, adopted on 25 November 2005.

- Article 29 Data Protection Working Party, Working document on the processing of personal data relating to health in electronic health records (EHR), 00323/07/EN, WP 131, adopted on 15 February 2007.

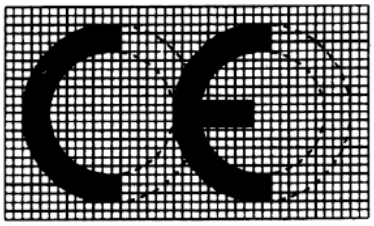
- Article 29 Data Protection Working Party, Working document on data protection issues related to RFID technology, 10107/05/EN, WP 105, adopted on 19 January, 2005.[26]

1.3.3 Medical Devices Directive 93/42/EEC[27]

The Medical Devices Directive was implemented on 14 June 1993 to define the essential requirements that medical devices must meet in order to be sold within the European Union.

Products conforming with the Medical Devices Directive are given a CE Mark[28] (shown below) that acts as a visual declaration by the manufacturer that the product meets all the appropriate provisions of the legislation. The CE mark also means that the product can be freely marketed anywhere in the EU without further control.

[24] These objectives are stated in the Tasks established for Article 29 as per http://ec.europa.eu/justice_home/fsj/privacy/docs/wpdocs/tasks-art-29_en.pdf.
[25] http://ec.europa.eu/justice_home/fsj/privacy/workinggroup/wpdocs/2009_en.htm
[26] RFID technology will not be a component in the initial LLM pilot and service releases; however, the technology may be added in a future release of the service.
[27] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31993L0042:EN:HTML
[28] http://www.mhra.gov.uk/home/groups/es-era/documents/publication/con007490.pdf



The CE Mark of Conformity

The Medical Devices Directive is primarily intended to remove barriers to trade amongst Member States and to bring about a single medical devices market in Europe.

Given that the LLM solution may not be considered a medical device (LLM's status as a medical device is under review in each of the pilot countries), but rather a support to independent living, this specific directive may not apply. If the specifications of the system are changed in a manner that require it to be tested and regulated as a medical device, these and other issues would need to be considered. Note that components of the LLM solution may nonetheless be required to have the CE Mark (i.e., electrical/electronic equipment) and other specific technical standards may apply in each country. Refer to the discussion for each country in the following sections for more information on any other technical requirements.

1.3.4 LLM Trials and Implications for Ethical Integrity and Data Protection

The LLM project will fully comply with all EU legislation and directives as stated above. In addition, the individual consortium partners will adhere to their national regulation and directives regarding the protection of personal data associated with LLM pilot trial participants and end-product users of the LLM system.

The aim of the LLM project is to deliver an integrated ICT solution that will provide cognitive and physical training for elderly people inside the framework and safety of an assisted living environment. Because the pilot trials and development of the product will rely heavily on the collection and storage of data that pertains to elderly human subjects, the legal directives and principles stated above must be strictly adhered to, which will include but not be limited to the following:

- Every trial participant will give his informed consent to taking part in the trial (research activity). The LLM Consent Form is included in Section 9 of this report.
- Every trial participant will be informed of his right to withdraw from the trial (research activity) at any time.
- Every trial participant may, without being subject to any resulting detriment, withdraw from the trial (research activity) at any time by revoking his informed consent.
- Information will be provided to every LLM trial participant to enable them to contact the LLM program coordinators directly for free access to all the information concerning him in clear language.
- The processing of personal data will comply with the eight enforceable principles of good practice as stated in Directive 95/46/EC. As such, the data will be:
    1. Fairly and lawfully processed.

2. Processed for limited purposes.
3. Adequate, relevant and not excessive.
4. Accurate.
5. Not kept longer than necessary.
6. Processed in accordance with the data subject's rights.
7. Secure and confidential.
8. Not transferred to countries without adequate protection.

- Every LLM trial participant will be able to directly require that their data be corrected (if they are wrong), completed or clarified (if they are incomplete or equivocal), or erased (if this information could not legally be collected).
- No LLM trial data will be disclosed to third parties.
- The trial data will only be accessed by those analysing the results of the pilot in each country. If data is to be shared within the project consortium, it will be shared anonymously.
- When collected data are used for dissemination purposes or other purposes exposing the data to the public, the data will be anonymous.
- Every LLM trial participant will be informed about the identity of the data controller and their representative, the purposes of processing; whether the data subject has the obligation to provide the information and the consequences of not doing so; the possible recipients of the data.
- With respect to sensitive data, the processing of racial and ethnic origins, the political, philosophical, religious opinions or trade union affiliation of persons, or the processing of data concerning their health or sexual life, is prohibited, except in cases established by the Law. The LLM trial will include the processing of health related data, but this data will be anonymised to protect the individual, in accordance with national legislation and European directives.
- The LLM project data controller will adopt all the necessary measures, with regard to the nature of the data and the risks of the processing, in order to preserve the security of the data.
- All data processing will be done according to an explicit end purpose.
- The dignity of all participants will be respected and protected.
- Complete anonymity of participants will be used throughout the course of the trials.
- Transmissions to third-parties for attention under exception conditions only will not include any detailed personal or location data pertaining to the elderly subject.
- Regarding informed consent, special care will be taken with respect to providing full disclosure about the pilot programme, its technological and privacy implications, to the end-users. Best practices will be employed in ensuring that participants have been fully informed of these implications, and are able to provide consent, with the end-user's consent (as compared to that of relatives, physicians, etc.) taking primacy. 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 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.

- All the research activities will be in compliance with fundamental ethical principles.
- The LLM trials will be registered in a publicly accessible database before recruitment of the first subject, follow all legal and ethical protocols, and obtain the appropriate permissions from the ethics committee(s) as required by national law.

1.4 European Group on Ethics in Science and New Technologies (EGE)[29]

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.

One such Opinion issued by the EGE that has the potential to affect the LLM project is **Opinion 13[30]: Ethical Issues of Healthcare in the Information Society (30 July 1999)**. The Opinion addressed the Status of Personal Health Data, Confidentiality/Privacy rights, Self-determination rights, Accountability, the Principle of Legitimate Purpose, Security, New ICT Technologies, Participation, Transparency, Evaluation, Education and Training, and Actions to Be Undertaken.

As per Article 1.1.1, the range of data covered by the Opinion is as follows:

> "The present Opinion confines itself to the ethical implications of the use of person identifiable personal health data. Person identifiable data includes, as in the terms of the Directive 95/46/EEC, any data which either directly or indirectly identifies an individual by reference to her/his name, identification number or to one or more factors specific to her/his physical, physiological, mental, economic, cultural or social identity."

[29] http://ec.europa.eu/european_group_ethics/index_en.htm
[30] http://ec.europa.eu/european_group_ethics/docs/avis13_en.pdf

And according to Article 1.5.3, the ethical principles are established as follows:

- In addition to the legal regulations, certain ethical principles may be used to address these value conflicts, namely:
  - Human dignity, serving as a basis for requirements of privacy, confidentiality and medical secrecy;
  - Autonomy, serving as a basis for requirements of self-determination and participation;
  - Justice, serving as a basis for requirements of equitable distribution of limited resources;
  - Beneficence and non-maleficence, serving as a basis for the attempts to weigh anticipated benefits against foreseeable risks;
  - Solidarity, serving as a basis of the right for everyone to the protection of healthcare, with a special concern for vulnerable groups in society.

1.5 Summary

Table 1: European Legislation/Directives

Legislation/Directives	Principles/Scope
Charter of Fundamental Rights of the European Union	Dignity, freedoms, equality, solidarity, citizens' rights and justice.
The European Human Rights Convention	Basic human rights, liberties and freedoms.
European Commission's Seventh Framework Programme (2007-2013)	Rules for the participation of undertakings, research centres and universities; ethical principles.
Directive 95/46/EC of the European Parliament and of the Council	Protection of individuals with regard to the processing of personal data and the free movement of such data.
World Medical Association Declaration of Helsinki	Statement of ethical principles for medical research involving human subjects.
Convention for the Protection of Individuals with regard to Automatic Processing of Personal Data (ETS No. 108)	Strengthen the protection of individuals with regard to the automatic processing of personal data.
Directive 2001/20/EC	Guidances on the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use.
GCP CPMP/ICH135/95 (Annex to Directive 75/318/EEC as amended)	Guidelines that should be followed when generating clinical trial data.
Directive 2000/C 364/01	The protection of personal data is a fundamental right.
Directive 2002/58/EC	Processing of personal data and the protection of

Table 1: European Legislation/Directives	
Legislation/Directives	**Principles/Scope**
	privacy in the electronic communications sector.
Directive 97/66/EC	Processing of personal data and the protection of privacy in the telecommunications sector.
Directive 2006/24/EC	Retention of data generated or processed in connection with the provision of publicly available electronic communications services.
Regulation (EC) 45/2001	Protection of individuals with regard to the processing of personal data by the Community institutions and bodies and on the free movement of such data.
Organisations	**Mission**
Clinical Trial Database Collection - EudraCT	Clinical trials database which contains all information regarding the content, commencement and termination of all clinical trials in the European Union.
European Network of Research Ethics Committees (EUREC)	Aims at the development of high quality standards in clinical trials in order to protect human subjects.
European Data Protection Supervisor (EDPS)	Devoted to protecting personal data and privacy and promoting good practice in the EU institutions and bodies.
Article 29 Data Protection Working Party	Consider and provide opinions on various data protection issues.
European Group on Ethics in Science and New Technologies (EGE)	Incorporate ethics into the decision-making process for community research and technological development policies.

2 NATIONAL REGULATION/LEGISLATION – AUSTRIA

2.1 National Regulatory Framework

The Data Protection Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 serves as the reference text for data protection issues throughout Europe, and also requires that each Member State set up an independent national body responsible for the protection of these data. The national regulatory framework pertaining to clinical trials and data protection in Austria is discussed in this section. However, please note that the target of the Austria LLM-trial is the validation of the LLM service, with its main focus being on usability and end-user-acceptance, and is not based on *clinical* or *medical* approval.

2.1.1 Federal Act concerning the Protection of Personal Data (Datenschutzgesetz 2000 – DSG 2000)[31]

In Austria, the right to data protection and privacy is a fundamental right, as stated in the Federal Act concerning the Protection of Personal Data, passed in 1999 to ensure that Austria complied with Directive 95/46/EC. This act has been in force since 1 January 2000.

The act provides for a fundamental right to privacy with respect to the processing of personal data which entails the right to information, rectification of incorrect data and erasure of unlawfully processed data. Specifically, **Section 1 (1)** states that:

> "Everybody shall have the right to secrecy for the personal data concerning him, especially with regard to his private and family life, insofar as he has an interest deserving such protection. Such an interest is precluded when data cannot be subject to the right to secrecy due to their general availability or because they cannot be traced back to the data subject [Betroffener]."

Furthermore, **Sect. 6. (1)** states that:

"Data shall only:

1. be used fairly and lawfully;
2. be collected for specific, explicit and legitimate purposes and not further processed in a way incompatible with those purposes; further uses for scientific and statistical purposes is permitted subject to sect. 46 and 47;
3. be used insofar as they are essential for the purpose of the data application [Datenanwendung] and are not excessive in relation to the purpose;
4. be used so that the results are factually correct with regard to the purpose of the application, and the data must be kept up to date when necessary;
5. be kept in a form which permits identification of data subjects [Betroffene] as long as this is necessary for the purpose for which the data were

[31] http://www.ris.bka.gv.at/Dokumente/Erv/ERV_1999_1_165/ERV_1999_1_165.pdf

collected; a longer period of storage may be laid down in specific laws, particularly laws concerning archives."

Additional guidelines specified in this Act regarding the use and protection of data include:

- Use of Data
- Data Security
- Publicity of Data Applications
- Rights of the Data Subject
- Legal Remedies
- Control Bodies
- Special Purposes of Data Use
- Special Uses of Data
- Penal Provisions
- Transitional and Final Provisions

2.2 Trial Approval Process

In Austria, medical clinical trials are regulated by the following:

- "Arzneimittelgesetz" (AMG, BGBl. I Nr. 63/2009) for pharmaceutical products and
- "Medizinproduktegesetz" (MÜG, BGBL I Nr. 77/2008) for any other kind of medical products.

All medical clinical trials must be performed in good understanding with the regional ethics commission (established by the Austrian ministry of health (BMG). For trials running in Schwechat, located in the federal country of Lower Austria (Niederoesterreich), that is the ethic commission of Lower Austria "Niederoesterreichische Ethikkommission.[32]"

However, the target of the Austrian LLM-trial is the validation of the LLM service, with its main focus being on usability and end-user-acceptance. Therefore, because there will not be a *clinical* or *medical* trial performed in Austria, the processes for approval of medical trials as foreseen in MPG (ch. 2.1.1) do not have to be fulfilled.

2.3 Trial Research

Other than the laws stated in this section, there are no additional specific laws covering research and development activities in Austria.

2.4 National Technical Standards

The devices used as parts of the LLM-system (electrical/electronic devices, training devices and devices declared as toys) must fulfill certain standards, as described in this section.

Standards for electronic/electrical devices must conform to European CE-regulations and must wear the CE-mark.

[32] http://www.noe.gv.at/Gesundheit/Gesundheitsvorsorge-Forschung/NOe-Ethikkommission.html

For training-devices, special standards must be fulfilled as described in detail by the following national standards:

- OENORM EN 957-01 …..general requirements for training devices
- OENORM EN 957-06 …..treadmills
- OENORM EN 957-10 …. ergometers and treadmills

2.5 Trial Data Protection Requirements

In Austria, the protection of personal data and the appropriate data privacy requirements are defined by the Federal Act concerning the Protection of Personal Data "Datenschutzgesetz 2000 (DSG 2000), BGBl. I Nr. 165/1999," as discussed above.

The use of personal data of test participants during the LLM pilot trials will be handled according to DSG 2000 article §46 (Scientific Research and Statistics), where the usage for scientific research is defined.

2.5.1 Usage of personal data of test persons

Usage of personal data will be handled according to one of the following clauses in DSG 2000:

- Usage of data is allowed without approval by DSK, if
  - data is only indirectly person-related or
  - data is used with consent of the affected persons
  - otherwise approval from the DSK is necessary.

2.5.2 Transfer of person-related data abroad

The DSG also describes transfer of person-related data abroad (DSK §12 and §13):

- Transfer of data is allowed without approval by DSK, if
  - data is only indirectly person-related or
  - with consent of the affected persons
  - and
    - the foreign institution declares to handle this transferred personal data according to the §11 of the DSG 2000 or
    - there exist in the foreign institution's country equivalent standards
  - in all other cases approval from the DSK is necessary

2.5.3 RALTEC's fulfillment of Austrian trial data requirements for LLM-project

Based on these facts, CEIT RALTEC will use the following proceeding for the Austrian LLM pilot trials:

- RALTEC has already placed its registration at the DVR,
- An informed consent for all persons affected in the pilot trials is prepared and is included in Section 9 of this report. This informed consent contains a clause that the affected person gives affirmation that the usage of personal data collected and stored within the LLM-project may be used by the LLM-consortium for scientific purposes.

- Cancellation by the affected person must be possible at every time without any implication to this person (see DSG 2000, §9, lit.6).

2.5.4 National Data Protection Commissioner of Austria

For the execution and control of the DSG 2000 a special commission "Datenschutzkommision" (DSK) has been established. Besides other tasks this commission handles the "Datenverarbeitungsregister" (DVR); entities handling personal data have to register themselves and according to the DSG 2000 their data applications.

Specifically, according to Part 4, Section 16 (1) of the Datenschutzgesetz 2000 (DSG 2000):

> **Sect. 16** (1) A register for data applications [Datenanwendungen] is established with the Data Protection Commission [Datenschutzkommission] for the purpose of examining their legality and in order to inform the data subjects [Betroffene].

National Data Protection Commissioner of Austria:
Österreichische Datenschutzkommission
Hohenstaufengasse 3
1010 Wien
Tel. +43 1 531 15 25 25
Fax +43 1 531 15 26 90
e-mail: dsk@dsk.gv.at
Website: http://www.dsk.gv.at/

2.6 Legal and Ethical Requirements – Implications for Technical and Pilot Design

2.6.1 Ethical requirements

The project is dealing with ICT based assistive and physical and psychological training technologies. Technical design and pilot execution is based by active involvement of potential end users. At the moment in Austria, there are no commonly approved guidelines that would help specifically in conducting technology evaluation in homes of elderly people, which is the pilot target of the Austrian pilot tests. The project uses the lessons learned from and guidelines developed in other projects of active end user involvement like the FRR-project (FP5), eHome (Austrian program FIT-IT), VitaliShoe (Austrian program benefit).

There is no official ethic commission research and development in the areas of assistive technologies and personal training systems. The only official site dealing with ethics is the Austrian "Bioethikkommision" (bio-ethic commission) at the "Bundeskanzleramt" (federal chancellor's office). The Austrian Bioethikkommision is mainly concerned with medical and biological issues. In 2009 this bio-ethic commission issued the first general statement on ethics in Assistive Technology in Austria, which is the result of a study about ethical aspects in development of assistive technologies, called "Ethische Aspekte der Entwicklung und des Einsatzes Assistiver

Technologien" (Bioethikkommission beim Bundeskanzleramt, Vienna, 2009). Concrete work in this field will be a question of future development and orientation of this Commission. Regardless, if this commission is already in a position to assist and/or evaluate the work of LLM, the publications and the opinions of the Bioethikkommission will be considered by RALTEC during the LLM-project.

Although the trials in Austria are planned as non-clinical trials the ethic commission of Lower Austria "Niederoesterreichische Ethikkommission" (see above) will be informed by RALTEC about the LLM-service and the test program prior to the start of the pilots.

Privacy:
The LLM project deals with an integrated solution combining computer based cognitive training (CTC), computer supported physical training (PTC) and an embedded PC based assistive smart home solution (ILC).

All three components can have an impact on the privacy of the end-user

- The CTC and the PTC are collecting and storing personal data (like name, address, but also health related data like heart rate, blood pressure, physical training results, psychological training results); from a legal point of view these facts are handled according to the Trial Data Protections requirements stated above.
- The ILC monitors the activities of daily life within a wireless local network, stores and analyzes these data locally. The ILC-component selected for the LLM-service, the eHome system uses this data in an ethical sound way: wireless data transmission is done encrypted and all the monitored data remains encapsulated at the end user's premises; data transfer to the outside is only performed after dedicated approval by the end user.

User recruitment:
The process of user recruitment is described in the pilot deployment plan (D4.1).

Concerning ethical requirements, special attention is turned on exclusion criteria: potential LLM test users are asked to get a declaration of no objection from their medical doctor; since a wireless networked electronic environment is used, people using a cardiac pacemaker are generally excluded.

Informed consent:
Because there are no specific rules in Austria regarding what informed consent must consist of, the one to be used in LLM is based on experiences from other European and national projects where end user involvement has been an important task, especially on the above mentioned eHome- and VitaliShoe-projects where RALTEC as a project-leader or project partner already has used special informed consents.

All users will receive appropriate information about the LLM-service, the objectives of the trial, the risks, benefits and alternatives of the research activity before they are asked for their consent. This will be done in a way appropriate to the situation of the potential users making sure that the information provided is clearly understood before

consent is asked for. This also includes clear information about the possibility to leave the research activity at any time without any consequences for the potential users.

Monitoring of the trials:
The managers of RALTEC and of "Seniorenzentrum SW" (senior's centre Schwechat, who is joining the LLM-consortium as partner #12) will observe the trial participants to ensure that the above defined guidelines for the project's pilot are followed.

2.6.2 Legal requirements

Insurance:
RALTEC owns appropriate liability insurance (K4-U069.170-1; Vienna Insurance Group) to assure pilot trial participants against personal damage.

2.7 Summary

Table 2: Austrian Legislation/Directives	
Legislation/Directives	**Principles/Scope**
Federal Act concerning the Protection of Personal Data (Datenschutzgesetz 2000 – DSG 2000)	Covers the fundamental rights of protection and privacy with respect to the processing of personal data.
Organisations	**Mission**
National Data Protection Commissioner of Austria - Datenschutzkommision (DSK)	The Data Protection Commission's role is to safeguard data protection in accordance with the regulations of the Datenschutzgesetz 2000. The Austrian Data Protection Council shares this role (DSG 2000, Part 7, s35 (1)).

3 NATIONAL REGULATION/LEGISLATION – CYPRUS

3.1 National Regulatory Framework

The Data Protection Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 serves as the reference text for data protection issues throughout Europe, and also requires that each Member State set up an independent national body responsible for the protection of these data. The national regulatory framework pertaining to clinical trials and data protection in Cyprus is discussed in this section. However, please note that the target of the Cypriot LLM-trial is the validation of the LLM service, with its main focus being on usability and end-user-acceptance, and is not based on *clinical* or *medical* approval.

3.1.1 Law of 2001: Processing of Personal Data Law (Protection of Individuals)[33]

The Processing of Personal Data (Protection of Individuals) Law of 2001 (N. 138/2001) was entered into force in November 2001, and is compliant with EU Directive 95/46.

The Law applies to living natural persons and covers automated, partially automated, and in some cases, non-automated processing operations, both in the public and the private sectors. It defines rights and obligations of controllers and data subjects, and sets the parameters for lawful processing of data. In order for the Law to be applicable, a data controller resident in the Republic must carry out the processing of personal data. The Law also applies at a place where Cyprus law is applied by virtue of public international law or by a data controller who is not resident in the Republic, who, for the purpose of processing personal data, has recourse to automated or other means existing in the Republic, unless they were used only for the purpose of transmitting the data through the Republic. The Law does not apply to the processing of personal data that is carried out by a natural person for the exercise of exclusively personal or domestic activities. In 2005 the European Commission notified the Office of the Commissioner for Personal Data Protection that certain sections of its Processing of Personal Data Law of 2001 did not fully comply with European Data Protection Directive. The discordant provisions dealt with the right of information, transfer of data to third countries and some procedural mechanisms. The Cyprus Office is preparing legislation to further harmonize these regulations with Directive 95/46/EC[34]

Note that the 2001 law discussed here was amended in 2003, through Law No. 37(I)/2003[35]. This amended the law under which processing for direct marketing purposes can take place. As such, this amendment does not affect the LLM project.

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33 http://www.dataprotection.gov.cy/dataprotection/dataprotection.nsf/697e70c0046f7759c2256e8c004a0a49/f8e24ef90a27f34fc2256eb4002854e7/$FILE/138%28I%29-2001_en.pdf

34 http://www.privacyinternational.org/article.shtml?cmd[347]=x-347-559499

35 http://www.dataprotection.gov.cy/dataprotection/dataprotection.nsf/697e70c0046f7759c2256e8c004a0a49/f8e24ef90a27f34fc2256eb4002854e7/$FILE/37%28I%29-2003_en.pdf

3.1.2 Law of 2004 (112(I)/2004): The Regulation of Electronic Communications and Postal Services[36]

In April 2004, the Regulation of Electronic Communications and Postal Services Law of 2004 was enacted.[37] This law regulates the secrecy of communications and the use of traffic and location data, telephone directories and unsolicited communications. It also particularizes and complements the provisions of the Law for the Processing of Personal Data.

- Part 14 of the Law transposing the provisions of the Directive on Privacy and Electronic Communications (2002/58/EC) regulates the secrecy of communications and the use of traffic and location data, telephone directories and unsolicited communications. It particularizes and complements the provisions of the Law for the Processing of Personal Data and provides for the protection of the legitimate interests of subscribers of electronic communications networks and services who are legal persons.
- Section 98 of the Law provides for the appropriate technical and organizational measures to be taken by providers of publicly available electronic communications services and networks to safeguard the security of their services and networks.
- Section 99 provides for the confidentiality of the communications and related traffic data.
- With regards to traffic data, Section 100 provides that such data relating to subscribers and users processed and stored by the provider of a public communications network or publicly available electronic communications service must be erased or made anonymous when it is no longer needed for the purpose of the transmission of a communication.

3.1.3 National Data Protection Commissioner of Cyprus

The Commissioner deals with the protection of personal information relating to an individual against its unauthorised and illegal collection, recording and further use and it also grants the individual certain rights, i.e. the right of information, the right of access and gives him the possibility to submit to the Office complaints relating to the application of the Law.

[36] http://www.dataprotection.gov.cy/dataprotection/dataprotection.nsf/697e70c0046f7759c2256e8c004a0a49/f8e24ef90a27f34fc2256eb4002854e7/$FILE/112%28I%29-2004_section106_en.pdf

[37] http://www.privacyinternational.org/article.shtml?cmd[347]=x-347-559499

Commissioner for Personal Data Protection
1 Iasonos Street
CY - 1082 Nicosia
P.O. Box 23378, CY-1682 Nicosia
Tel. +357 22 818 456
Fax +357 22 304 565
e-mail: commissioner@dataprotection.gov.cy
Website: http://www.dataprotection.gov.cy/

3.2 Trial Approval Process

In Cyprus the body responsible for any medical research or projects is the Cyprus National Bioethics Committee[38] (CNBC), established in 2001 by the Law No. 150 (I) of 2001, Law Providing for the Establishment and Function of the National Bioethics Committee. The CNBC is an independent body and is not subject to the administrative control of any ministry, independent officer, department or service and has the powers provided by the present or any other Law. All medical research or projects are subject to approval from this committee.

In accordance with article 3 (1) of the Law N. 150 (I) /2001 The Bioethics (Establishment and Function of the National Committee), the Committee`s mission is the constant monitoring, survey, systematic analysis and evaluation of the issues and problems that relate to the scientific research, progress and implementation of the sciences of biotechnology, biology, medicine, genetics and pharmaceutics as well as to the human intervention on the biological procedure and the human genotype and the investigation of their moral, deontological, social, humanistic and legal dimensions.[39]

The CNBC has 13 members, including the chairperson. The members represent different professions and disciplines, and are appointed by the Council of Ministers of the Republic of Cyprus for a term of office of four years. According to the provisions of the legislation, at least four members must emerge from the humanities and social sciences sector; four members must emerge from the area of medical and biological sciences, and four members from the area of any other science or profession or who are distinguished in any area of activity for their contribution.

The law files under which CNBC is functioning can be found online at: http://www.bioethics.gov.cy/Law/cnbc/cnbc.nsf/All/538006E398361B89C22571C9002B25A1?OpenDocument

All forms required by the Committee, including application, reporting and consent forms, can be found online at:
http://www.bioethics.gov.cy/Law/cnbc/cnbc.nsf/DMLapplform_en/DMLapplform_en?OpenDocument

[38] http://www.bioethics.gov.cy/Law/cnbc/cnbc.nsf/DMLindex_en/DMLindex_en?OpenDocument
[39] http://www.bioethics.gov.cy/Law/cnbc/cnbc.nsf/DMLmission_en/DMLmission_en?OpenDocument

The LLM Informed Consent Form, which must be completed by all program participants, is also included in Section 9 of this document: Annex – Supplementary Documents.

3.3 Trial Data Protection Requirements

Data protection in Cyprus is strictly governed by the Processing of Personal Data Law 138 (I) of 2001. According to Article 7(1), the controller (those collecting the data) "must notify the Commissioner in writing about the establishment and operation of a filing system or the commencement of processing."

In addition to the data protection standards as required by European legislation and listed in the first Chapter of this document, the following guidelines will be followed during the LLM pilot trial to comply with specific requirements as established by the Cypriot legal directives discussed above:

- Every LLM trial participant must give explicit consent to participate and for the sensitive data processing of information.
- Every LLM data subject can appeal to the Commissioner in order to analyze the filing system and processing of their data.
- Every LLM data subject has the right to be informed about the purposes of processing, the possible recipients of their data, the right of access and rectification and other special information relating to their specific data processing.
- Any participant may leave the trial at any time. All the participant has to do is inform the research team about her/his withdrawal from the trial, and give the reasons she/he has for doing so.
- If the LLM trial data is to be transmitted outside of Cyprus, approval from the Data Commissioner is necessary.
- All LLM data collection must be relevant, appropriate, and not excessive.
- All LLM data processing will be anonymous and confidential.

3.4 Legal and Ethical Requirements – Implications for Technical and Pilot Design

All LLM ethical considerations for Cyprus fall under the jurisdiction of the Cyprus National Bioethics Committee, discussed in detail above.

3.5 Summary

Table 3: Cypriot Legislation/Directives	
Legislation/Directives	**Principles/Scope**
Law of 2001: Processing of Personal Data Law (Protection of Individuals)	Implementation of EU Directive 95/46/EU in Cyprus.
Law of 2004 (112(I)/2004): The Regulation of Electronic Communications and Postal Services	Regulates the secrecy of communications and the use of traffic and location data, telephone directories and unsolicited communications. It particularizes and complements the provisions of the Law for the Processing of Personal Data.
Organisations	**Mission**
National Data Protection Commissioner of Cyprus	Oversees the implementation of the Data Protection Act and enforces its regulations.
Cyprus National Bioethics Committee (CNBC)	The Committee`s mission is the constant monitoring, survey, systematic analysis and evaluation of the issues and problems that relate to the scientific research, progress and implementation of the sciences of biotechnology, biology, medicine, genetics and pharmaceutics as well as to the human intervention on the biological procedure and the human genotype and the investigation of their moral, deontological, social, humanistic and legal dimensions.

4 NATIONAL REGULATION/LEGISLATION – FRANCE

4.1 National Regulatory Framework

The Data Protection Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 serves as the reference text for data protection issues throughout Europe, and also requires that each Member State set up an independent national body responsible for the protection of these data. The national regulatory framework pertaining to clinical trials and data protection in France is discussed in this section. However, please note that the target of the France LLM-trial is the validation of the LLM service, with its main focus being on usability and end-user-acceptance, and is not based on *clinical* or *medical* approval.

4.1.1 Huriet-Sérusclat and the Law of the 9th August 2004

On 20th December 1988, France passed the Huriet-Sérusclat Law which placed strict control over all persons involved in medical research. In 2004, (with the Law of the 9th August 2004), Huriet-Sérusclat was amended with the purpose of implementing Directive 2001/20/EC and further ensuring good practice in the conduct of clinical trials on medicinal products for human use and reinforcing the protection measures for persons participating in biomedical research.

4.1.2 French Data Protection Act 78-17

The French Data Protection Act no. 78-17 of 6 January 1978, as amended by Act no. 2004-801 of 6 August 2004 is the implementation of EU Directive 95/46/EU in France and follows the same broad protection requirements of similar legislation in the EU.

This act is based on two important principles:

- data processing should infringe neither human identity, nor human rights, nor privacy, nor individual or public liberties;
- any person is entitled to know and dispute the data and logic used in automatic processing the results of which are asserted against him.

In the same Act, France instituted an independent body on data protection and privacy, namely the National Data Processing and Liberties Commission (CNIL). This authority ensures observance of the 1978 Act and protects individuals' rights concerning where and how personal information is contained or used on computer files.

4.1.3 National Data Protection Commissioner of France:

Commission Nationale de l'Informatique et des Libertés (CNiL)
8, rue Vivienne, CS 30223
F-75002 Paris, CEDEX 02
Tel. +33 (0) 1 53 73 22 22
Fax +33 (0) 1 53 73 22 00
Website: http://www.cnil.fr/

4.2 Trial Approval Process

In France, clinical trials are strictly controlled by law. Several authorities are involved in the protection of clinical trial participants and any personal data collected and stored during medical research.

Before any public or private biomedical studies can take place, the organization undertaking the research must obtain the following approvals and/or take the following actions:

- The Agence Française de Sécurité Sanitaire des Produits de Santé (AFSSAPS), the French Health Products Safety Agency was created in 1998 with the purpose of strengthening health monitoring and control via evaluation, inspection and testing. AFSSAPS is the entry point for evaluating any product claiming a relation with "health." AFSSAPS may initiate investigations during a protocole via an independent 'Comité d'éthique' (committee on Ethics) and requires that patients give their "informed consent" to participate in any study. Upon being approved by AFSSAPS, the trial study team will receive a detailed recommended procedure regarding the trial to be undertaken.

- After approval from AFSSAPS, the research team must submit the data protection protocol to the National Consultative Committee on the processing of Information in the Health Sector, after which it will be referred for approval to the CNiL-Data Protection Supervisory Authority. CNiL (the Commission nationale de l'informatique et des libertés) is in charge of making sure human identity, private life and freedom are respected in the digital world. CNiL will then give authorisation for the processing of personal health data and supervise the use of such data.

- To protect the study participants, approval of the research protocol must be submitted to a Committee for the Protection of Persons (CPP - Comité de Protection des Personnes). The regional research ethics committee will issue an opinion to the researcher regarding the protection of the participants and whether any subsequent amendments to the research protocol are required. After the research protocol is approved by a CPP, it is then referred for approval to either the Ministry of Health or the Agency for the Sanitary Security of Health Products.

- All BPCs (bonnes pratiques cliniques – good clinical practice) must be respected.

- Any organization collecting or using personal data must declare its database to the French Data Protection Agency.

- Note that in France, it is not compulsory to appeal to an Ethics Committee.

4.3 Trial Data Protection Requirements

Trial data protection is paramount in any clinical trial and patient anonymity must be guaranteed. Only the "front end clinician" may know the human subject's identity, and all data must be "anonymised."

In addition to the data protection standards as required by European legislation and listed in the first Chapter of this document, the following guidelines will be followed during the LLM pilot trial to comply with specific requirements as established by the French legal directives discussed above:

- Every LLM trial participant may contact the CNiL to receive assistance in the exercise of his rights (particularly if his right of access has been denied).
- Every LLM trial participant must be informed about the identity of the data controller and their representative, the purposes of processing; whether the data subject has the obligation to provide the information and the consequences of not doing so; the possible recipients of the data.
- Any participant may leave the trial at any time. All the participant has to do is inform the research team about her/his withdrawal from the trial, and give the reasons she/he has for doing so.
- The transfer of data to other states depends on the level of data protection in that state, and will require authorization from the DPA.
- The French Data Protection Act provides that personal data cannot be stored over a certain period of time. Therefore, the French Data Protection Agency ensures that the storage time reflected in the declaration will not be disproportionate to the purpose of the database.

4.4 Legal and Ethical Requirements – Implications for Technical and Pilot Design

Discussions with Agence Française de Sécurité Sanitaire des Produits de Santé (AFSSAPS) have determined that the "product status" of LLM is i) not a medical device and ii) will be considered "hors produit de santé," is not a medicine.

However, the obligation remains to report the LLM pilot study experience to AFSSAPS, as well as to comply with all data and confidentiality legislative requirements. To accommodate these requirements, the LLM database design plans to have a French node as part of a distributed database, with access to anonymised French non-confidential information by all-LLM. All local French trial data will be maintained in this separate node. The current plan for implementing this design is via mySQL.

4.5 Summary

Table 3: French Legislation/Directives	
Legislation/Directives	**Principles/Scope**
Huriet-Sérusclat	Placed strict control over all persons involved in medical research and ensuring good practice in the conduct of clinical trials on medicinal products for human use.
French Data Protection Act 78-17	Implementation of EU Directive 95/46/EU in France.
Organisations	**Mission**
National Data Protection Commissioner of France	Oversees the implementation of the Data Protection Act and enforces its regulations.
National Data Processing and Liberties Commission (CNIL)	Ensures observance of the 1978 Act and protects individuals' rights concerning where and how personal information is contained or used on computer files.
Committee for the Protection of Persons (CPP)	Must approve all research protocols.
National Consultative Committee on the processing of Information in the Health Sector	Must approve the data protection protocol.
Agence Française de Sécurité Sanitaire des Produits de Santé (AFSSAPS)	The French Health Products Safety Agency for increasing medical safety and the protection of public health.

5 NATIONAL REGULATION/LEGISLATION – GERMANY

5.1 National Regulatory Framework

The Data Protection Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 serves as the reference text for data protection issues throughout Europe, and also requires that each Member State set up an independent national body responsible for the protection of these data. The national regulatory framework pertaining to data protection in Germany is discussed in this section.

Note that while the LLM pilot will not be conducted in Germany, the consortium is represented in that country, and thus, only non-pilot related legislation (i.e., that may impact the design of the LLM solution) is examined in this section.

5.1.1 The Federal Data Protection Act (Bundesdatenschutzgesetz)

The Federal Data Protection Act (Bundesdatenschutzgesetz) was adopted on May 18th, 2001, printed in the Bundesgesetzblatt I Nr. 23/2001 on May 22nd, 2001 as the implementation of EU Directive 95/46/EC in Germany and covers the protection of data held by Federal public authorities as well as private sector organizations.

The act adheres to the seven basic principles of EU Directive 95/46/EC in the protection of data relating to individuals or data that allows an individual to be identified.

In addition, the 16 Länder (Brandenburg, Baden-Württemberg, Bayern, Hessen. Nordrhein-Westfalen, Schleswig- Holstein) have their own data protection regulations that cover local public bodies. These local regulations are similar in spirit to the Federal Data Protection Act.

5.1.2 National Data Protection Commissioner of Germany:

Der Bundesbeauftragte für den Datenschutz und die Informationsfreiheit
Husarenstraße 30
53117 Bonn
Tel. +49 (0) 228 997799 0 or +49 (0) 228 81995 0
Fax +49 (0) 228 997799 550 or +49 (0) 228 81995 550
e-mail: poststelle@bfdi.bund.de
Website: http://www.bfdi.bund.de/cln_134/Vorschaltseite_DE_node.html

5.2 Trial Approval Process

This section is not applicable, because no LLM trial will be conducted in Germany.

5.3 Trial Data Protection Requirements

This section is not applicable, because no LLM trial will be conducted in Germany.

5.4 Summary

Table 4: Germany Legislation/Directives	
Legislation/Directives	**Principles/Scope**
The Federal Data Protection Act (Bundesdatenschutzgesetz)	Implementation of EU Directive 95/46/EC in Germany and covers the protection of data held by Federal public authorities as well as private sector organizations.
Organisations	**Mission**
National Data Protection Commissioner of Germany	Oversees the implementation of the Data Protection Act and enforces its regulations.

6 NATIONAL REGULATION/LEGISLATION – GREECE

6.1 National Regulatory Framework

The Data Protection Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 serves as the reference text for data protection issues throughout Europe, and also requires that each Member State set up an independent national body responsible for the protection of these data. The national regulatory framework pertaining to clinical trials and data protection in Greece is discussed in this section. However, please note that the target of the Greece LLM-trial is the validation of the LLM service, with its main focus being on usability and end-user-acceptance, and is not based on *clinical* or *medical* approval.

6.1.1 Law 2472/1997

The national regulatory framework related to the LLM pilot studies in Greece is mainly detailed in law 2472/1997 "on the Protection of Individuals with regard to the Processing of Personal Data[40]" as amended by Laws 2819/2000 and 2915/2000. According to article 15, the Personal Data Protection Authority is responsible for the implementation of this law and all other regulations pertaining to the protection of individuals from the processing of personal data.

Other existing laws and public authorities responsible for the approval and supervision of clinical trials which include the administration of *pharmaceutical* substances are not applicable here.

6.1.2 Law 3471/2006

Protection of personal data and privacy in the electronic telecommunications sector and amendment of law 2472/1997.

6.1.3 National Data Protection Commissioner of Greece

Hellenic Data Protection Authority
Kifisias Av. 1-3, PC 11523
Ampelokipi Athens, Greece
Tel. +30 210 6475 600
Fax +30 210 6475 628
e-mail: contact@dpa.gr
Website:
http://www.dpa.gr/portal/page?_pageid=33,15048&_dad=portal&_schema=PORTAL

40 As defined in article 2, case a, as "…any information relating to the data subject. Personal data are not considered to be the consolidated data of a statistical nature where data subjects may no longer be identified."

6.2 Trial Approval Process

The collection and processing[41] of sensitive data[42] requires permission from the Data Protection Authority. More specifically, according to article 7, "The collection and processing of sensitive data is prohibited". Exceptionally, the collection and processing of sensitive data, as well as the establishment and operation of the relevant file[43], will be permitted by the Authority[44], when at least one of several requirements are met, including:

- The data subject[45] has given his/her written consent[46] (7.2a).
- Processing is carried out exclusively for research and scientific purposes provided that anonymity is maintained and all necessary measures for the protection of the persons involved are taken (article 7.2f).

The Controller[47] must notify the Authority in writing about the establishment and operation of a file or the commencement of data processing (7.3).

The Authority will grant a permit for the collection and processing of sensitive data, which will be issued for a specific period of time, depending on the purpose of data processing, and which may be renewed upon request of the Controller, as well as a permit for the establishment and operation of the relevant file (7.3, 7.4).

The permit, a copy of which will be kept by the Authority, will contain information including the name and address of the Controller and the place where the file is established, the categories of personal data which are allowed to be included in the file, the time period for which the permit is granted, the terms and conditions, if any, imposed by the Authority etc.

Any change in the above must be communicated to the Authority and may entail the issuance of a new permit (7.5, 7.6, 7.7).

To our knowledge, there are no other legal requirements with regard to the trial approval process. Non pharmaceutical clinical studies do not require permission from public authorities such as the National Organization of Medicines and there are no standard protocols for conducting pilot studies.

41 As defined in article 2, case d, as "…any operation or set of operations which is performed upon personal data by Public Administration or by a public law entity or private law entity or an association or a natural person, whether or not by automatic means, such as collection, recording, organisation, preservation or storage, modification, retrieval, use, disclosure by transmission, dissemination or otherwise making available, correlation or combination, interconnection, blocking (locking), erasure or destruction."

42 which, according to article 2, case b, includes data referring to the health condition of the data subjects

43 As defined in article 2, case e, as "…any structured set of personal data which are accessible on the basis of specific criteria"

44 As defined in article 2, case l, as "…the Authority for the Protection of Personal Data"

45 As defined in article 2, case c, as "…any natural person to whom such data refer and whose identity is known or may be found, i.e., his/her identity may be determined directly or indirectly, in particular by reference to an identity card number or to one or more factors specific to his/her physical, physiological, mental, economic, cultural, political or social identity."

46 As defined in article 2, case k, as "…any freely given, explicit and specific indication of will, whereby the data subject expressly and fully cognisant signifies his/her informed agreement to personal data relating to him being processed. Such information shall include at least information as to the purpose of processing, the data or data categories being processed, the recipient or categories of recipients of personal data as well as the name, trade name and address of the Controller and his/her representative, if any. Such consent may be revoked at any time without retroactive effect."

47 As defined in article 2, case g, as "…any person who determines the scope and means of the processing of personal data, such as any natural or legal person, public authority or agency or any other organisation"

6.3 Trial Data Protection Requirements

According to article 4 of Law 2472/1997, personal data in order to be lawfully processed must meet certain requirements. They must be collected fairly and lawfully, for specific and legitimate purposes and processed in view of such purposes, be relevant and not excessive in relation to the purposes for which they are processed, be accurate and up to date and kept in a form which permits identification of data subjects for no longer than the period required, according to the Authority. Once this period of time is lapsed, the Authority may allow the maintenance of personal data for historical, scientific or statistical purposes, provided that it considers that the rights of the data subjects are not violated in any given case. The Controller must ensure compliance with these provisions.

According to article 10:

- The processing of personal data must be confidential and carried out solely and exclusively by persons acting under the authority of the Controller or the Processor[48] and upon his/ her instructions.
- The Controller must choose persons with professional qualifications providing sufficient guarantees with respect to their technical expertise and personal integrity. He must implement appropriate organisational and technical measures to secure data and protect them against accidental or unlawful destruction, accidental loss, alteration, unauthorised disclosure or access as well as any other form of unlawful processing. Such measures must ensure a level of security appropriate to the risks presented by processing and the nature of the data subject to processing. The Authority will offer instructions and issue regulations involving the level of security of data and of the computer and information infrastructure, the security measures that are required for each category and processing of data as well as the use of technology for the strengthening of privacy (amended as above by article 25 of Law 3471/2006, Official Gazette 133A/2006).
- If the data processing is carried out on behalf of the Controller, by a person not dependent upon him, the assignment must necessarily be in writing and must provide that the Processor carries out such data processing only on instructions from the Controller.

According to article 9, the transfer of personal data is permitted for member-states of the European Union.

According to articles 11, 12 and 13, there are certain requirements that must be met, regarding the data subjects' right to information, access and objections:

- The Controller must, during the stage of collection of personal data, inform the data subject in writing about his identity and the identity of his representative, if any, the purpose of data processing, the recipients or the categories of recipients of such data and the data subjects' rights. If the data are to be disclosed to third parties, the data subject will be kept informed of such disclosure before it is effected (article 11).

[48] defined in article 2, case h, as "…any person who processes personal data on behalf of a Controller, such as any natural person or legal person, public authority or agency or any other organisation"

- Everyone is entitled to know whether personal data relating to him are being processed or have been processed (article 12).
- The data subject can object at any time to the processing of data relating to him. Such objections will be addressed in writing to the Controller and must contain a request for a specific action, such as correction, temporary non-use, deletion etc. The Controller must reply in writing to such objection within fifteen days.

6.4 Legal and Ethical Requirements – Implications for Technical and Pilot Design

Although there are no legal requirements for the notification of other public authorities other than the Data Protection Authority, we can inform the National Organization for Medicines as well as the administrative council of every pilot site about the upcoming pilots.

6.5 Summary

Table 5: Greece Legislation/Directives	
Legislation/Directives	**Principles/Scope**
Law 2472/1997	Protects 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.
Organisations	**Mission**
National Data Protection Commissioner of Greece	Oversees the implementation of the Data Protection Act and enforces its regulations.

7 NATIONAL REGULATION/LEGISLATION – SPAIN

7.1 National Regulatory Framework

The Data Protection Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 serves as the reference text for data protection issues throughout Europe, and also requires that each Member State set up an independent national body responsible for the protection of these data. The national regulatory framework pertaining to clinical trials and data protection in Spain is discussed in this section. However, please note that the target of the Spain LLM-trial is the validation of the LLM service, with its main focus being on usability and end-user-acceptance, and is not based on *clinical* or *medical* approval.

7.1.1 Ley Orgánica 15/1999[49]

According to the Spanish Constitution, data protection is a constitutional right in Spain. Specifically, Article 18.4 of the Constitution states 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, which was then subsequently amended by Organic Law 15/1999, thus implementing Directive 95/46/EC into Spanish law.

On December 21, 2007, the Spanish Council of Ministers adopted a royal decree (Royal Decree 1720/2007[50]) that fully implemented Organic Law 15/1999 on the protection of personal data.

7.1.2 Real Decreto 223/2004[51]

On May 1, 2004, the Spanish Real Decreto 223/2004 replaced the Real Decreto 561/1993, which established the requirements for the conduct of clinical trials with medicinal products.

This Royal Decree includes the European Community guidelines in relation to good practice standards in clinical trials with medicinal products and therefore transposes Directive 2001/20/EC into Spanish legislation.

7.1.3 Ley 41/2002

The object of Law 41/2002 of 14 November 2002 is the regulation of the rights and obligations of patients, users and professionals, as well as of public and private

[49] An unofficial translation can be found at: https://www.agpd.es/upload/ley_15_ingles_v2_pdf.pdf. Please note that the only legally binding text is that published in the Spanish Official Journal (BOE 298, 14 December 1999).
[50] https://www.agpd.es/portalweb/english_resources/common/reglamentolopd_en.pdf
[51] http://www.boe.es/boe/dias/2004/02/07/pdfs/A05429-05443.pdf

healthcare centres and services, with regard to the autonomy of the patient and of clinical information and documentation.

Basic principles:

1. The dignity of the individual, the respect for the autonomy of his/her will and for his/her privacy will orientate the obtaining, use, archiving, keeping, and transfer of clinical information and documentation.
2. All actions require the prior consent of the patients or users, this consent will be given in writing as foreseen in the law.
3. The patient or user has the right to decide freely between the clinical options available.
4. Every patient or user has the right to refuse treatment, except in the cases determined in the Law.
5. The patients or users have the obligation to give information about their health in a trustworthy and truthful fashion.
6. Every healthcare professional is obligated to lend his/her services correctly, and to comply with obligations regarding clinical information and documentation, and to respect the decisions of the patient.
7. The person that produces or has access to clinical information and documentation is obliged to keep it in confidence.

Rights that are regulated:

1. Right to healthcare information (the holder of the right is the patient, though people related to him/her will also be informed. These relations may be familial or of fact, according to the permission of the patient)
2. Right to epidemiological information.
3. Right to privacy.
4. Right to information for the choice of doctor and centre.
5. Right to access to clinical history.
6. Rights related to the keeping of clinical history.

In this law, the respect for the autonomy of the patient is regulated via informed consent, expressing its limits, the conditions of the information that it must contain, whether it be verbal or written.

This law considers clinical history, its definition, archiving and conservation, as well as the content that it must include and it use. Access to it for judicial, epidemiological, public health, research or teaching reasons is subject the Organic Law 15/1999 and the Law 14/1986.

Likewise the discharge of the patient, discharge report, and the issue of medical certificates are regulated.

7.1.4 Spanish Autonomous Communities and Health Care

The 1978 Spanish Constitution established a region-based Autonomous organisation of the national territory that allowed the devolution of Communities' central health care powers to the Autonomous Communities. Under health care constitutional provisions and their respective Statues of Autonomy, Autonomous Communities have

gradually assumed such legal authority. The health care devolution process, managed by the National Institute of Health (INSALUD), began in 1981 and ended in 2002, with the central government retaining the responsibility for health care management in the Autonomous Cities of Ceuta and Melilla, through the National Health Management Institute (INGESA). Therefore, the Autonomous Communities exercise their powers and duties in the following areas: health planning; public health; health care. They have, therefore, taken on the functions and services, goods, rights and duties relative to such powers, as well as the staff and budgets assigned to them.

Each Autonomous Community has a regional health service, which is the administrative and management body responsible for all the centres, services, and facilities in its Community, whether these are organised by regional or town councils, or any other intra-community administration.

The principles governing health coordination on a nationwide level are set forth in the General Health Act 14/1986 of 25 April, which also specified collaboration instruments and established the Interterritorial Council of the National Health System (CISNS, from its Spanish abbreviation) as the coordinating body.

Subsequently, Act 16/2003 of 28 May on Cohesion and Quality in the National Health System deals in greater depth with the role of the Interterritorial Council as the coordinating body and with general coordination and cooperation within the National Health System.

The devolution of powers to Autonomous Communities is a means of bringing health care management closer to citizens, thus guaranteeing equity, quality and participation. Practical experience of relations between the central government and the Autonomous Communities governments relative to health protection provide important references for the development of cohesion in the State of Autonomous Communities. All parties involved work together to achieve a common identity for the National Health System, based on the constitutional principles of unity, autonomy and solidarity.

The Act on Cohesion and Quality in the National Health System therefore establishes coordination and cooperation amongst the country's public health care managements to guarantee the right of all citizens to health protection and care, and to ensure:

a) equity, in keeping with the constitutional principle of equality, guaranteeing access to services and therefore recognizing the right to health protection and care with the same level of efficacy throughout the Spanish territory, thus enabling citizens to move freely throughout the national territory;
b) quality, by putting into use safe and effective innovations and orientating the system towards the anticipation and effective solution of health problems, evaluating the benefits of clinical actions so that only those that improve health are taken, and involving all agents in the work of the system;
c) citizen participation, by acknowledging their autonomy regarding individual decisions and by taking into account their expectations as users of the health system, to facilitate the exchange of knowledge and experience.

Process of devolution of INSALUD

Autonomous community	Royal Decree
Cataluña	1517/1981, 8 July
Andalucía	400/1984, 22 February
País Vasco	1536/1987, 6 November
Comunidad Valenciana	1612/1987, 27 November
Galicia	1679/1990, 28 December
Navarra	1680/1990, 28 December
Canarias	446/1994, 11 March
Asturias	1471/2001, 27 December
Cantabria	1472/2001, 27 December
La Rioja	1473/2001, 27 December
Murcia	1474/2001, 27 December
Aragón	1475/2001, 27 December
Castilla-La Mancha	1476/2001, 27 December
Extremadura	1477/2001, 27 December
Baleares	1478/2001, 27 December
Madrid	1479/2001, 27 December
Castilla y León	1480/2001, 27 December

7.1.5 National Data Protection Commissioner of Spain

Agencia de Protección de Datos
C/Jorge Juan, 6
E - 28001 MADRID
Tel. +34 91399 6200
Fax +34 91455 5699
e-mail: internacional@agpd.es
Website: https://www.agpd.es/portalweb/index-ides-idphp.php

7.2 Trial Approval Process

In 1990, with the introduction of the Ley del Medicamento[52], "Clinical Research Ethics Committees (CEICs)" were formally established in order to assess methodological, ethical and legal aspects of the protocol as well as the benefit/risk balance of all clinical trials to take place in Spain. The authority that authorises each clinical research ethics committee is the regional government. There are 18 CEICs throughout Spain.

According to the Spanish law [223/2004], a Clinical Research Ethics Committee must approve all research projects involving human participants.

[52] http://www.aemps.es/actividad/legislacion/espana/docs/RCL_1990_2643-2006-3.pdf

The procedure for authorising a clinical trial in Spain is the following[53]:

1. For all trials, an application must be submitted to all CEICs covering the areas where the trial will be performed (between the 1st to the 5th day of the same month).
2. An application must be submitted to the responsible authority, the Spanish Medicines Agency (Agencia Espanola de Medicamentos y Productos Sanitarios - AEMP).
   There is an online application through the Internet where all involved committees must provide their comments on the protocol.
3. Finally, after assessing the comments from all the involved committees, the 'reference CEIC' provides its final 'single opinion'.
4. There is also a requirement for the budget of each study, and each site, to be submitted to the CEIC.

The established timelines for the assessment of single- and multi-site studies is 60 days according to the regulations.

The LLM database will be also registered on the Spanish Data Protection Agency (Agencia Española de Protección de Datos), fulfilling the requirement to notify this Agency of transfers of personal data between EU member states.

7.3 Trial Data Protection Requirements

The Articles in the LOPD 15/1999 that apply to data protection for LLM are as follows:

Article 4. Quality of the data

1. Personal data may be collected for processing, and undergo such processing, only if they are adequate, relevant and not excessive in relation to the scope and the specified, explicit and legitimate purposes for which they were obtained.
2. Personal data subjected to processing may not be used for purposes incompatible with those for which they were collected. Further processing of the data for historical, statistical or scientific purposes shall not be considered incompatible.
3. Personal data shall be accurate and updated in such a way as to give a true picture of the current situation of the data subject.
4. If the personal data recorded prove to be inaccurate, either in whole or in part, or incomplete, shall be erased and officially replaced by the corresponding rectified or supplemented data, without prejudice to the rights granted to data subjects in Article 16.
5. Personal data shall be erased when they have ceased to be necessary or relevant for the purpose for which they were obtained or recorded.
   They shall not be kept in a form which permits identification of the data subject for longer than necessary for the purposes for which they were obtained or recorded.

[53] The steps noted here were obtained from the EUREC website: http://www.eurecnet.org/information/spain.html

On a regular basis, the procedure shall be determined by which, exceptionally, it is decided to keep the entire set of particular data, in accordance with the specific legislation, because of their historical, statistical or scientific value.

6. Personal data shall be stored in a way which permits the right of access to be exercised, unless lawfully erased.
   The collection of data by fraudulent, unfair or illicit means is prohibited.

Article 5. Right of information in the collection of data

1. Data subjects from who personal data are requested must previously be informed explicitly, precisely and unequivocally of the following:
   a) The existence of a file or personal data processing operation, the purpose of collecting the data, and the recipients of the information.
   b) The obligatory or voluntary nature of the reply to the questions put to them.
   c) The consequences of obtaining the data or of refusing to provide them.
   d) The possibility of exercising rights of access, rectification, erasure and objection.
   e) The identity and address of the controller or of his representative, if any.
   Where the controller is not established on the territory of the European Union, and he is using for the processing means situated on Spanish territory, he must, unless these means are being used for transit purposes, designate a representative in Spain, without prejudice to any action which may be taken against the controller himself.
2. Where questionnaires or other forms are used for collection, they must contain the warnings set out in the previous paragraph in a clearly legible form.
3. The information set out in subparagraphs (b), (c) and (d) of paragraph 1 shall not be required if its content can be clearly deduced from the nature of the personal data requested or the circumstances in which they are obtained.
4. Where the personal data have not been obtained from the data subject, he must be informed explicitly, precisely and unequivocally by the controller or his representative within three months from the recording of the data - unless he has been informed previously - of the content of the processing, the origin of the data, and the information set out in (a), (d) and (e) of paragraph 1 of this Article.
5. The provisions of the preceding paragraph shall not apply where explicitly provided for by law, when the processing is for historical, statistical or scientific purposes, or when it is not possible to inform the data subject, or where this would involve a disproportionate effort in the view of the Data Protection Agency or the corresponding regional body, in view of the number of data subjects, the age of the data and the possible compensatory measures.
   The provisions of the preceding paragraph shall also not apply where the data come from sources accessible to the public and are intended for advertising activity or market research, in which case each communication sent to the data subject shall inform him of the origin of the data, the identity of the controller and the rights of the data subject.

Article 6. Consent of the data subject

1. Processing of personal data shall require the unambiguous consent of the data subject, unless laid down otherwise by law.

2. Consent shall not be required where the personal data are collected for the exercise of the functions proper to public administrations within the scope of their responsibilities; where they relate to the parties to a contract or preliminary contract for a business, employment or administrative relationship, and are necessary for its maintenance or fulfillment; where the purpose of processing the data is to protect a vital interest of the data subject under the terms of Article 7(6) of this Law, or where the data are contained in sources accessible to the public and their processing is necessary to satisfy the legitimate interest pursued by the controller or that of the third party to whom the data are communicated, unless the fundamental rights and freedoms of the data subject are jeopardised.
3. The consent to which the Article refers may be revoked when there are justified grounds for doing so and the revocation does not have retroactive effect.
4. In the cases where the consent of the data subject is not required for processing personal data, and unless provided otherwise by law, the data subject may object to such processing when there are compelling and legitimate grounds relating to a particular personal situation. In such an event, the controller shall exclude the data relating to the data subject from the processing.

Article 8. Data on health

Without prejudice to the provisions of Article 11 on assignment, public and private health-care institutions and centres and the corresponding professionals may process personal data relating to the health of persons consulting them or admitted to them for treatment, in accordance with the provisions of the central or regional government legislation on health care.

Article 9. Data security

1. The controller or, where applicable, the processor shall adopt the technical and organisational measures necessary to ensure the security of the personal data and prevent their alteration, loss, unauthorised processing or access, having regard to the state of the art, the nature of the data stored and the risks to which they are exposed by virtue of human action or the physical or natural environment.
2. No personal data shall be recorded in files which do not meet the conditions laid down by rules regarding their integrity and security, as well as the rules governing the processing centres, premises, equipment, systems and programs.
3. Rules shall be laid down governing the requirements and conditions to be met by the files and the persons involved in the data processing referred to in Article 7 of this Law.

Article 10. Duty of secrecy

The controller and any persons involved in any stage of processing personal data shall be subject to professional secrecy as regards such data and to the duty to keep them. These obligations shall continue even after the end of the relations with the owner of the file or, where applicable, the person responsible for it.

Article 11. Communication of data

1. Personal data subjected to processing may be communicated to third persons only for purposes directly related to the legitimate functions of the transferor and transferee with the prior consent of the data subject.

2. The consent required under the previous paragraph shall not be required:
   a) when the transfer is authorised by a law.
   b) when the data have been collected from publicly accessible sources.
   c) when the processing corresponds to the free and legitimate acceptance of a legal relationship whose course, performance and monitoring necessarily involve the connection between such processing and files of third parties. In that case, communication shall be legitimate to the extent of the purpose justifying it.
   d) when the communication to be effected is destined for the Ombudsman, the Office of Public Prosecutor, judges, courts or the Court of Auditors in the exercise of the functions assigned to them. Not shall consent be required when the communication is destined to regional government authorities with functions analogous to the Ombudsman or the Court of Auditors.
   e) when the transfer is between public administrations and concerns the retrospective processing of the data for historical, statistical or scientific purposes.
   f) when the transfer of personal data on health is necessary for resolving an emergency which requires access to a file or for conducting epidemiological studies within the meaning of central or regional government health legislation.
3. Consent for the communication of personal data to a third party shall be null and void when the information given to the data subject does not enable him to know the purpose for which the data whose communications is authorised will be used or the type of activity of the person to whom it is intended to communicate them.
4. Consent for the communication of personal data may also be revoked.
5. The person to who personal data are communicated is obliged, by the mere fact of the communication, to abide by the provisions of this Law.
6. If the communication is preceded by a depersonalisation procedure, the provisions of the preceding paragraphs shall not apply.

Article 15. Right of access

1. The data subject shall have the right to request and obtain free of charge information on his personal data subjected to processing, on the origin of such data and on their communication or intended communication.
2. The information may be obtained by simply displaying the data for consultation or by indicating the data subjected to processing in writing, or in a copy, fax or photocopy, whether certified a true copy or not, in legible and intelligible form, and without using keys or codes which require the use of specific devices.
3. The right of access referred to in this Article may be exercised only at intervals of not less than twelve months, unless the data subject can prove a legitimate interest in doing so, in which case it may be exercised before then.

Article 16. Right of rectification or cancellation

1. The controller shall be obliged to implement the right of rectification or cancellation of the data subject within a period of ten days.
2. Rectification or cancellation shall apply to data whose processing is not in accordance with the provisions of this Law and, in particular, when such data are incorrect or incomplete.

3. Cancellation shall lead to the data being blocked and maintained solely at the disposal of the public administrations, judges and courts, for the purpose of determining any liability arising from the processing, and for the duration of such liability. On expiry of such liability, they shall be deleted.
4. If the data rectified or cancelled have previously been communicated, the controller shall notify the person to whom they have been communicated of the rectification or cancellation. If the processing is being maintained by that person, he shall also cancel the data.
5. Personal data shall be kept for the periods set out in the relevant provisions or, where applicable, in the contractual relations between the person or body responsible for the processing ("the controller") and the data subject.

Article 30. Processing for the purpose of publicity and market research

1. Those involved in compiling addresses, disseminating documents, publicity, distance selling, market research or other similar activities shall use names and addresses or other personal data when they feature in sources accessible to the public or when they have been provided by the data subjects themselves or with their consent.
2. When the data come from sources accessible to the public, in accordance with the provisions of the second paragraph of Article 5.5 of this Law, each communication sent to the data subject shall indicate the origin of the data and the identity of the controller, as well as the rights available to the data subject.
3. In exercising the right of access, data subjects shall have the right to know the origin of their personal data and the rest of the information referred to in Article 15.
4. Data subjects shall have the right to object, upon request and free of charge, to the processing of the data concerning them, in which case they shall be deleted from the processing and, at their mere request, the information about them contained in the processing shall be cancelled.

7.4 Summary

Table 6: Spain Legislation/Directives	
Legislation/Directives	**Principles/Scope**
Ley Orgánica 15/1999 (LOPD)	Protects the honour and the personal and family privacy of Spanish citizens, including their personal data.
Real Decreto 223/2004	Established the requirements for the conduct of clinical trials with medicinal products and defines good practice standards in clinical trials with medicinal products.
Ley 41/2002	Regulates the rights and obligations of patients, users and professionals, as well as of public and private healthcare centres and services, with regard to the autonomy of the patient and of clinical information and documentation.
Organisations	**Mission**
National Data Protection Commissioner of Spain	Oversees the implementation of the Data Protection Act and enforces its regulations.
The Data Protection Agency of the Community of Madrid, the Basque Data Protection Agency, and the Data Protection Agency of Catalonia.	Responsible for the processing and files of the regional administrative bodies.
Clinical Research Ethics Committees (CEICs)	Assess the methodological, ethical and legal aspects of the protocol as well as the benefit/risk balance of all clinical trials to take place in Spain.
Spanish Medicines Agency (Agencia Espanola de Medicamentos y Productos Sanitarios - AEMP)	Approves all clinical trials to take place in Spain.

8 NATIONAL REGULATION/LEGISLATION – UK

8.1 National Regulatory Framework

The Data Protection Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 serves as the reference text for data protection issues throughout Europe, and also requires that each Member State set up an independent national body responsible for the protection of these data. The national regulatory framework pertaining to clinical trials and data protection in the UK is discussed in this section.

Note that although the LLM pilot will not be conducted in the UK, the consortium is represented in that country and as such, related legislation (i.e., that may impact the design of the LLM solution) is examined in this section.

8.1.1 Data Protection Act 1998[54]

The Data Protection Act of 1984 was the first legislation in the UK pertaining to data protection, and only applied to data stored on a computer. In 1997, the elected Labour government finally agreed to place the issue of Data Protection on its agenda as a part of a wider concern for human rights. The Data Protection Act passed on 16 July 1998 implemented Directive 95/46/EC and transposed the EC directive into UK law.

The Data Protection Act of 1998 gives UK citizens the right to know what information is held about them, and sets out rules to make sure that this information is protected and handled properly. The Act applies to all public and private organizations that process personal data and requires them to comply with eight data protection principles discussed later in this section.

8.1.2 Information Commissioner's Office[55] (ICO)

The ICO is the UK's independent authority for promoting data privacy. The ICO is responsible for promoting good practice by data controllers and ensuring that personal information isn't misused. If members of the public think they're being prevented from seeing information they're entitled to, they can ask the ICO for help.

8.1.3 Social Research Association[56]

The Social Research Association (SRA) was established in 1978 and is responsible for advancing the conduct, development, and application of social research. The Association is open to practitioners and researchers interested in all branches of social research, and maintains an up-to-date set of Ethical Guidelines[57] that are widely adopted as standards in research ethics.

[54] http://www.opsi.gov.uk/acts/acts1998/ukpga_19980029_en_1
[55] http://www.ico.gov.uk/
[56] http://www.the-sra.org.uk/index.htm
[57] http://www.the-sra.org.uk/ethical.htm

8.1.4 Research Ethics Committees (RECs)

Research Ethics Committees provide independent advice to participants, researchers, funders, sponsors, employers, care organisations and professionals regarding whether proposals for research studies comply with recognised ethical standards. The standards framework for all RECs are listed in detail in the Governance arrangements for NHS Research Ethics Committees (July 2001)[58].

Currently there are two kinds of RECs in the UK:

- Local Research Ethics Committees (LRECs) - The LREC system was organised initially by Department of Health Guidance in 1991 in England and Wales and in 1992 in Scotland. LRECs are responsible for reviewing protocols conducted in their own area.
- Multi-centre Research Ethics Committees (MRECs) - The MREC system was created in 1997. MRECs are responsible of reviewing protocols held in more than four locations.

8.1.5 Medicines for Human Use (Clinical Trials) Regulation 2004

This Regulation implemented Directive 2001/20 and regulated the ethical review system of clinical trials. This created the United Kingdom Ethics Committee Authority (UKECA) to authorise and oversee the Research Ethics Committees.

8.1.6 National Research Ethics Service (NRES)[59]

The UK Department of Health authorised the National Research Ethics Service (NRES) within the National Patient Safety Agency to co-ordinate the development of operational systems for NHS RECs. NRES is responsible for providing ethical guidance to RECs by facilitating ethical research while protecting the rights, dignity and safety of research participants.

In April 2009, NRES updated their Standard Operating Procedures for Research Ethics Committees[60] which meets the obligations of the United Kingdom under Directive 2001/20/EC of the European Parliament and the Council of the European Union ("the EU Directive") for the operation of ethics committees in relation to clinical trials of investigational medicinal products.

8.1.7 National Data Protection Commissioner of the UK

Information Commissioner
The Office of the Information Commissioner Executive Department
Water Lane, Wycliffe House
UK - WILMSLOW - CHESHIRE SK9 5AF

58 http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/documents/digitalasset/dh_4058609.pdf

59 http://www.nres.npsa.nhs.uk/

60 http://www.nres.npsa.nhs.uk/EasySiteWeb/GatewayLink.aspx?alId=27094

Tel. +44 1 625 54 57 00 (switchboard)
e-mail: please use the online enquiry from our website
Website: https://www.ico.gov.uk/Global/contact_us.aspx

8.2 Trial Approval Process

- To process personal data in the UK, requires notification of the Information Commissioner. Notification includes details on how the organisation intends to process personal data and whether there are any sensitivity issues. The Information Commissioner will enter the general details into a publicly accessible register.
- For clinical trials, permission is also required from the Medicines and Healthcare Products Regulatory Agency (MHRA)[61].
- The research sponsor is also required to ensure that a favourable opinion on the ethics of the proposed research has been obtained from an appropriate REC. It is the responsibility of the named principal investigator to apply for approval by the REC. This person retains responsibility for the scientific and ethical conduct of the research.

Note: No pilot studies will be executed in the UK, but this information is included as background.

8.3 Trial Data Protection Requirements

- The Data Protection Act of 1998 applies to all public and private organizations that process personal data and requires them to comply with the following eight data protection principles[62]:

1. Personal data shall be processed fairly and lawfully and, in particular, shall not be processed unless –
   (a) at least one of the conditions in Schedule 2 is met, and
   (b) in the case of sensitive personal data, at least one of the conditions in Schedule 3 is also met.
2. 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.
3. Personal data shall be adequate, relevant and not excessive in relation to the purpose or purposes for which they are processed.
4. Personal data shall be accurate and, where necessary, kept up to date.
5. Personal data processed for any purpose or purposes shall not be kept for longer than is necessary for that purpose or those purposes.
6. Personal data shall be processed in accordance with the rights of data subjects under this Act.
7. 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.

[61] http://www.mhra.gov.uk/index.htm
[62] http://www.opsi.gov.uk/Acts/Acts1998/ukpga_19980029_en_9#sch1-pt1

8. Personal data shall not be transferred to a country or territory outside the European Economic Area unless that country or territory ensures an adequate level of protection for the rights and freedoms of data subjects in relation to the processing of personal data.

- Schedule 2[63] of the Data Protection Act specifies "Conditions Relevant for Purposes of the First Principle: Processing of Any Personal Data." Those conditions relevant to the LLM project include the following:

1. The data subject has given his consent to the processing.
2. The processing is necessary—
   (a) for the performance of a contract to which the data subject is a party, or
   (b) for the taking of steps at the request of the data subject with a view to entering into a contract.
3. The processing is necessary for compliance with any legal obligation to which the data controller is subject, other than an obligation imposed by contract.
4. The processing is necessary in order to protect the vital interests of the data subject.

- Schedule 3[64] of the Data Protection Act specifies "Conditions Relevant for Purposes of the First Principle: Processing of Sensitive Personal Data." Those conditions relevant to the LLM project include the following:

1. The data subject has given his explicit consent to the processing of the personal data.
4. The processing—
   (a) is carried out in the course of its legitimate activities by anybody or association which—
      (i) is not established or conducted for profit, and
      (ii) exists for political, philosophical, religious or trade-union purposes,
   (b) is carried out with appropriate safeguards for the rights and freedoms of data subjects,
   (c) relates only to individuals who either are members of the body or association or have regular contact with it in connection with its purposes, and
   (d) does not involve disclosure of the personal data to a third party without the consent of the data subject.

- The Data Protection Act requires that appropriate security measures are in place to guard against unauthorized use or disclosure of the stored personal data, or its accidental loss or destruction. Encryption may be a part of the information security arrangements, but it is not required.

[63] http://www.opsi.gov.uk/Acts/Acts1998/ukpga_19980029_en_10#sch2
[64] http://www.opsi.gov.uk/Acts/Acts1998/ukpga_19980029_en_10#sch3

- Anonymisation consists of both stripping data of all personal identifiers and destroying the original dataset.

- Informed consent is not required by the Data Protection Act of 1998; however, the Information Commissioner Office's Legal Guidance recommends reliance on the EU Data Protection Directive. Section 7(1) of the Data Protection Act gives individuals the right to access their personal data. By making a written request and paying a fee, an individual is entitled to see (among other things):
  - the information which is the personal data; and
  - any information available to the data controller about the source of the data.

- Section 10 of the Data Protection Act confers to individuals the right to prevent processing likely to cause damage or distress.

- Section 33[65] of the Data Protection Act lists the exemptions to the processing of personal data collected for "research purposes," in particular:
  - data are not processed in such a way that substantial damage or substantial distress is, or is likely to be, caused to any data subject
  - the further processing of personal data only for research purposes in compliance with the relevant conditions is not to be regarded as incompatible with the purposes for which they were obtained.
  - Personal data which are processed only for research purposes in compliance with the relevant conditions may, notwithstanding the fifth data protection principle, be kept indefinitely.

8.4 Legal and Ethical Requirements – Implications for Technical and Pilot Design

8.4.1 Legal Requirements

In the UK, all medical devices must comply with the Essential Requirements for medical devices as outlined in the EC Medical Devices Directive 93/42/EEC in order to be approved by the Medicines and Healthcare Products Regulatory Agency (MHRA). Upon complying with the appropriate Essential Requirements, the product is allowed to carry the CE Marking and may be marketed anywhere in the EU without further regulation.

In order to show compliance with the Medical Devices Directive 93/42/EEC, the manufacturer can choose between different Conformity Assessment Procedures (outlined in MHRA Bulletin No 4[66]), and where appropriate, select a Notified Body (outlined in MHRA Bulletin 6[67]) to carry out these procedures.

In the UK, the "Notified Body" is the Medicines and Healthcare Products Regulatory Agency (MHRA) as defined in MHRA Bulletin 6:

[65] http://www.opsi.gov.uk/Acts/Acts1998/ukpga_19980029_en_5#pt4-l1g33
[66] http://www.mhra.gov.uk/home/groups/es-era/documents/publication/con007492.pdf
[67] http://www.mhra.gov.uk/home/groups/es-era/documents/publication/con007493.pdf

> "A Notified Body is a certification organisation which the national authority (the Competent Authority) of a Member State designates to carry out one or more of the conformity assessment procedures described in the annexes of the Directives. The Medicines & Healthcare Products Regulatory Agency is the UK Competent Authority under the three Medical Devices Directives."

8.4.2 Ethical Requirements

In the UK, comprehensive ethics reviews are required to protect individuals involved in clinical research. The following framework has been designed with research in mind, but can be adhered to to ensure those same high ethical standards in the LLM pilot design and product implementation.

Research Governance Framework for Health and Social Care[68]
The following principles in this framework can be applied to the LLM pilot:

- All organisations conducting, sponsoring, funding or hosting health and social care research must put in place systems to ensure that they and their staff understand and follow the standards and good practice set out in this framework.
- They must have access to independent expert review that enables the main funder and the sponsor to be satisfied of the scientific and ethical standing of the work, its strategic relevance and value for money.
- The appropriate use and protection of patient data is also paramount.
- Relevant service users and carers or their representative groups should be involved wherever possible in the design, conduct, analysis and reporting of research.
- When a study involves participants under the care of a doctor, nurse or social worker for the condition to which the study relates, those care professionals are informed that their patients or users are being invited to participate, and agree to retain overall responsibility for their care.
- Procedures are kept in place to ensure collection of high quality, accurate data and the integrity and confidentiality of data during processing and storage.
- Delivery systems should be designed to facilitate adherence to requirements and to detect failures, whether such failures arise by intent or oversight. These systems should include a risk-based programme of routine and random monitoring and audit. They should require, facilitate and support reporting of critical incidents, near-misses, systems failures and misconduct either by self-reporting or whistle-blowing.

[68] http://www.oncoreuk.org/downloads/DOH.pdf

8.5 Summary

Table 7: UK Legislation/Directives	
Legislation/Directives	**Principles/Scope**
Data Protection Act 1998	Gives UK citizens the right to know what information is held about them, and sets out rules to make sure that this information is protected and handled properly
Medicines for Human Use (Clinical Trials) Regulation 2004	Implemented Directive 2001/20 and regulated the ethical review system of clinical trials
Organisations	**Mission**
National Data Protection Commissioner of the UK	Oversees the implementation of the Data Protection Act and enforces its regulations.
Information Commissioner's Office	Responsible for promoting good practice by data controllers and ensuring that personal information isn't misused.
Social Research Association (SRA)	Responsible for advancing the conduct, development, and application of social research.
Central Office for Research Ethics Committees (COREC)	Responsible for authorising and overseeing RECs.
Medicines and Healthcare Products Regulatory Agency (MHRA)	Enhances and safeguards the health of the public by ensuring that medicines and medical devices work and are acceptably safe.

9 Annex – Supplementary Documents

9.1 Long Lasting Memories Informed Consent Form

LONG LASTING MEMORIES (LLM) – INFORMATION AND INFORMED CONSENT
[two signed copies needed – one for the participant and one for the study coordinator]

1. LLM project funding and study coordinator

The Long Lasting Memories (LLM) project is funded by the European Commission and conducted in 5 different EU countries. Your responsible study coordinator is *[to be filled in from each pilot site]*

Name: _____ Tel: _____

2. Aim of the LLM project

Current research indicates that there are positive effects of sensory and physical training on cognitive health. However, both types of training have mainly been tested separately. This project aims at investigating the potentially positive effects on cognitive and physical health of a combined sensory-cognitive and physical training for persons aged 60 years compared to a passive or active control group. At some locations, sensors will be used as a supplement to the training in order to detect risk and frequency of falls during daily routines within private households or senior care centers.

3. LLM project procedure

After you have given your informed written consent for voluntary LLM project participation you will participate in cognitive and physical tests including:

- questions concerning your living conditions, medical history, social engagement, etc.
- neuropsychological tests regarding memory, speech, speed of processing, attention, etc.
- physical fitness tests

Provided that you fulfill all the necessary requirements and do not fulfill any exclusion criteria, you will be randomly assigned either to an intervention group or a control group. The intervention will take place over a period of 8 consecutive weeks, and will be conducted as a structured training program.

The training will be carried out 5 times a week, lasting 1-2 hours in each session, and using several computer components (including a screen and the Wii™ system). Although computers are used in the program, there is no need for you to know anything about them, and the training is very simple and easy to use. Both the sensory-cognitive and physical training components will automatically be adapted to your needs.

Those assigned to the control group will have wait for 8 weeks until they are eligible to participate in one of the training programs. Nevertheless, all tests will be applied in exactly the same time frame as usual.

After 8 weeks of training or waiting, all the tests and questionnaires from the beginning of the project will be repeated in order to analyze potential effects of training compared to waiting on the cognitive and physical capabilities of all participants. Depending on the project location, some of the tests might be repeated a third time, 3 months after the conclusion of 8 weeks training or waiting.

4. Risks of LLM project participation

The neuropsychological tests as well as the sensory-cognitive training component do not imply any known risks for cognitive or physical health.

Physical fitness tests and physical training components will be designed in a manner that should not create any health risks to the individual. Before participating, each person will be asked to confirm with his or her (primary) physician that it will be safe for him or her to join. Without signed approval of the (primary) physician, LLM project participation will not be possible.

5. LLM project costs and payments

There is no cost to participate in the LLM project; costs for tests and training will be redeemed by the LLM project. Volunteers will not receive any payments for participating.

6. Rights within the LLM project

LLM project participation is voluntary. Participation does not imply any debts or duties. You have the right to end your participation in the LLM project 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 project.

Volunteers who receive access to training software and equipment are bound to treat these training materials with caution in order to prevent damage. Training materials are not allowed to be given or to be disclosed to any third parties.

7. Data privacy and protection

Data will be collected and analyzed throughout the whole LLM project participation (e.g., about the cognitive and physical health of each participant at the beginning and ending of the project). Data will be stored in an anonymous form on computers that are connected to the internet. However, there is no legal option for external people (non-LLM project members) to get access to these data. This information will be used solely for scientific and technical research purposes. All LLM project members are bound to data discretion. Project results might be published in research journals. Nevertheless, there will never be the possibility to trace personal data for any participant.

8. Informed Consent

I _____
(name, first name of the participant in block letters)

b. _____
(DD/MM/YYYY)

do volunteer for participating in the LLM project. I have read and understood the preceding project information.

I have been sufficiently informed about aims and contents of the LLM project including tests, training procedures, potential risks, and costs. My questions have been sufficiently answered.

I have been given sufficient time to decide upon my LLM project participation.

I know that I can quit LLM project participation at any time (in written form or verbally) – even without giving reasons – without any negative consequences.

I know that all personal data will be stored and analyzed anonymously and that all LLM project members with access to my personal data are bound to data discretion.

_____ _____

Date, signature of participant Date, signature of interviewer/ researcher

Enrollment No: _____

LLM project checklist

Who can participate?	Adults over the age of 60 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 LLM project.
What is the cost of the LLM project?	There is no cost to participate in the LLM project, and volunteers will not receive any payments for participating.
What is the level of commitment a participant needs to make?	The LLM programme will be conducted for a period of 8 weeks. Each participant of the intervention group will do specific physical activities and/or sensory-cognitive exercises (on a computer) for 1-2 hours sessions 5 times per week. The control group will have to wait for at least 8 weeks before they can start the training programme. Before and after the training or waiting period the participant will be tested with a series of cognitive and physical fitness tests in order to track potential training success.
Do I need to know anything	No. Although computers are used in the training, there is no need for you to know anything about them, and the training is

about computers to participate?	very simple and easy to use.
What are the risks?	Both the physical activity and the sensory-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 the Wii™ system, along with activities initially 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 LLM project.
Can I get access to the information gathered about me during the LLM project?	Yes. While details about each individual's health will be stored in an anonymous form on computer systems, it is possible to provide a test and/or training report after you have finished the LLM project. Some training results will be presented immediately after each training session.
Can I drop out of the LLM project?	Yes. You have the right to end your participation in the LLM project 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 LLM project.