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1 INTRODUCTION

This deliverable aims at providing a legal and ethical framework for the Florence Project. Even though some aspects were identified already in D1.2 and D1.4 due to the necessary user involvement during focus groups and The Wizard of Oz test, a more rationalised and legal insight is provided in this document.

It will provide an overview of all the specific regulations and legislation at European and national level which are applicable to the scope of the project, taking into account than non specific medical records or measurements are intended to be used, and that moreover, the activities of the robotic integrated platform are related to social and quality of life improvement services. Therefore, there are separate sections explaining different levels: from the European framework to the specific Florence project specification.

Furthermore, there is an overview of the concrete documents needed to meet the legal and ethical standards as well as a section on the protocol to be complied with, when it comes to decommissioning of the equipment and the steps to follow to mitigate the potential setback of getting used to the piloted Florence service, so that the user does not feel in need once the pilot is finished.

Following that approach, this deliverable will finally provide a description of each of the sites testing labs and their conditions in order to analyse the environment in which the users will be involved and interact with a prototype in real home environments (Telefónica) and controlled environments (Philips and OFFIS). This description will allow for a comprehensive methodology in later stages of WP5 and will set the conditions to screen users' involvement against the ethical and legal requirements.

2 Ethical and Legal Regulation

2.1 European approach

The general regulations of the European Union are declared in the Charter of Fundamental Rights of the European Union (2000/C 364/01). Within this charter, the following articles addresses in `particular the issues dealt with by the Florence project.

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

- Everyone has the right to the protection of personal data concerning him or her.
- Such data must be processed fairly for specified purposes and on the basis of the consent of the person concerned or some other legitimate basis laid down by law. Everyone has the right of access to data which has been collected concerning him or her, and the right to have it rectified.
- Compliance with these rules shall be subject to control by an independent authority.

Article 25 deals with end-users and “recognizes and respects the rights of the elderly to lead a life of dignity and independence and to participate in social and cultural life”. The next article, number 26, deals with integration of persons with disabilities. The article states that: “The Union recognizes and respects the right of persons with disabilities to benefit from measures designed to ensure their independence, social and occupational integration and participation in the life of the community”.

Within the above mentioned fundamental rights, processing of personal data and protection of privacy is also dealt with in Directive95/46/EC. A number of requirements have been set down in relation to confidentiality and security which tele-monitoring has to follow to ensure individuals’ rights. Member states are obliged by the Commission protocol to notify each other and the Commission before adopting any technical regulations or information society services, in the national laws.

The “Universal Service Directive 2002 for telephone services” enables national regulators to introduce measures that help to make access to basic telephone services affordable to low income and special needs groups. It is more focused on basic telephone and communication services.

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

2.2 National Regulations

2.2.1 Germany

In Germany data protection is based on the Federal Data Protection Act (BDSG). This was first promulgated on 14 January 2003 and last lamented on 14 August 2009. The purpose of this Act is to protect individuals against infringement of their right to privacy as the result of the handling of their personal data:

- Section 3a: “Personal data shall be collected, processed and used, and data processing systems shall be chosen and organized in accordance with the aim of collecting, processing and using as little personal data as possible. In particular, personal data shall be rendered anonymous or aliased as allowed by the purpose for which they are collected and/or further processed, and as far as the effort required is not disproportionate to the desired purpose of protection.”
- Section 4 (3): “If personal data are collected from the data subject, the controller shall inform him/her as to:
  - The identity of the controller,
  - The purposes of collection, processing or use, and
  - The categories of recipients only where, given the circumstances of the individual case, the data subject need not expect that his/her data will be transferred to such recipients,
  - Unless the data subject is already aware of this information. If personal data are collected from the data subject pursuant to a law requiring the provision of such information, or if providing this information is required for the granting of legal benefits, the data subject shall be informed that providing this information is required or voluntary, as the case may be. The law and the consequences of refusing to provide information shall be explained to the data subject as necessary in the individual case.

There is no central ethical commission (EC) for the review of individual biomedical projects. The members of the “Deutscher Ethikrat”, as established by legislation of the “Deutscher Bundestag” on April 26, 2007, have been appointed recently by the “Deutscher Bundestag”. The “Deutscher Ethikrat” has started his work and may give recommendations which are not binding.

There is however the Central Ethics Committee of the German Medical Association (Zentrale Ethikkommission bei der Bundesärztekammer) which gives opinions on general ethical issues and which may give advice to the ECs of the Medical Associations at their request. This advice is in no way binding on the ECs.

Defined by the different States legislations the competent EC which is responsible for the coordinating investigator is either the EC at the Medical Association or at the university, depending on the location of that investigator. ECs are competent for all research projects including research using removed biological materials of human origin and personal data.

The following laws for data protection and health care are the base for the decisions of the ECs:

- Federal laws covering the areas of the health care system:
- Legislation on the statutory health insurance (Social Security Code, Book V)
- Law on Long-Term Care Insurance (Social Security Code, Book XI)
- Drug Law
- Medical Devices Act
- Training regulations for doctors, dentists, veterinarians, psychotherapists and for non-physician health care professionals
- Hospitals Financing Act
- Narcotics Act

- Protection Against Infection Act

2.2.2 Spain

In this section, we will mention the main juridical items concerning regulations while piloting. The items are ordered by importance.

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

  This law tries to warrant and protect personal data concerning treatment of public freedoms and basic rights of the physical persons, especially for personal and family privacy. This law corresponds to the European legislation. Article 7 deals with data related to information on testing of health in particular. In the Royal Decree 1720/2007, the Rule Development of Personal Data Protection Law is approved. This Decree tries to face the possible risks of Personal data treatment.

- Equal opportunity, no discrimination and universal accessibility of handicapped people: Independent living / accessibility 51/2003 (Cachón, 2006):

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

- Public Health Act 14/1986:

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

Royal Decree 994/1999

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

In the contents of the Royal Decree 994/1999 on “security measures of automated databases which contain personal information” and also in Law 41/2002 “regulatory base of the patient’s autonomy and of rights and obligations regarding clinical information and documentation”, current Spanish legislation already explicitly covers both the specific need to guarantee secure access to and custody of huge amounts of sensitive information (social or medical) [Royal Decree 1999] [LAW 2002].

Specifically, article 19 of Law 41/2002 on the safety of medical information directly deals with the rights of patients so “that Health Centres establish an active and diligent mechanism to safeguard medical records” and article 16 of the law includes in this safekeeping the obligation to allow “the collection, integration, recuperation and communication of the information considered confidential”.

It is particularly interesting for tele-assistance to underline the fact that article IV of Royal Decree 994/1999 contemplates the fact that the security measures for databases that include personal health data need to be considered “high level” or a maximum requirement. This classification implies and requires what is outlined in the following article as regards the distribution of information, access logging and the use of data transmission and communication services:

Article 23: Distribution of IT Media
The distribution of media containing personal data will be done with the data encoded or using some other mechanism that guarantees that the data cannot be understood or manipulated during the transfer.

Article 24: Access Logging
At least the information on the user's identification, the date and time of access, the data accessed and whether access was authorised or denied will be stored.

Article 26: Telecommunications

The transmission of personal data over telecommunication networks will be done with the data encoded or using some other mechanism that guarantees that the data cannot be understood or manipulated by third parties.

Furthermore, the new Law 39/2006 of 14 December on the Promotion of Personal Autonomy and Care of those in dependent situations contemplates in article 4 that a fundamental right of those persons in dependent situations is the enjoyment of "human rights and fundamental freedoms with full respect for their dignity and privacy".

The application of the legislation in force is a matter for all the organisms and institutions that have some kind of responsibility for attending to persons in dependent situations, according to Law 39/2006 of 14 December on the Promotion of Personal Autonomy and Care of those in dependent situations.

These institutions are the Autonomous Regions, which then delegate competency to Town Councils, County Councils or Private Companies.

2.2.3 The Netherlands

According to Dutch law, when dealing with ethical issues related to trials that involve humans (or animals, but this does not concern Florence) there is a substantial difference between two cases:

(1) The trials are related to devices, procedures or substances used for medical purposes and
(2) Other types of trials. In the first case, there are strict rules to conduct such trials, and there is a regulatory body, called Medical Ethics Committee, whose approval is needed before starting the trials.

In the second case, and this is the case for Florence, there are no such strict rules. The Dutch law (or more precisely, the part called "general liability") stipulates that this is a sole responsibility of a device manufacturer, and the designer of trials, to take all necessary and reasonable precautions, before the trials, to ensure the rights, safety and well-being of the test subjects.

2.3 Application of actual regulation to Florence trials

Ethical issues will be considered during all stages of Florence project, according to the European, national and regional laws and regulations listed above. Some of these issues have already arisen during the first stage of the project: User centric service definition, as end users have been involved in the different methods used in WP1 (focus groups, Wizard of Oz, etc.).The methodology followed regarding these ethical issues is described briefly in D.1.2 when referring to these methods, and is described in detail in this section, according to the different rules and procedures used in each of the sites. Also an overview of the ethical issues for the living lab is described, but the definitive methodology will be further defined in D.6.2, once the use cases to be

implemented in the real lab testing are selected and the involvement of final users in these tests is described in detail.

2.3.1 Germany

All data produced by the Florence project in Germany has to comply to the German laws and regulations. These regulations are stated in the previous section . Data privacy has a high priority in Germany and the use of personal data is strictly regulated. Participants of studies etc. have to give their consent for the use of any data. If human beings are involved in the studies and trials, also ethical boards have to give an approval. So for the Florence Focus Group sessions as well as the controlled home environment tests a check with the current regulations and/or an approval of the ethical commissions has to be done

2.3.2 Spain

Concerning the Spanish regulations described before the preliminary issue to take into account for Florence project is to accomplish the aforementioned Organic law 15/1999 of Personal Data Protection. FASS and Telefónica I+D as an organization has its own audited procedures of keeping and coding data giving id numbers to identities. This process is checked out regularly by external companies in order to renovate the quality and benchmarking mentions. The implication of the management of personal information transcends this law and also meets other regulations and standards such as the Royal Decree 994/1986.

The second important issue of legal and ethical requirements applied under Florence trials is the obligation to inform about the project and end up with a legal paper called informed consent (explained in detail in the next section). This practise comes from the Public Health Act 14/1986 in which it states that all relevant information must be given to the user.

Finally, as a derivative of the previous law but non mandatory, comes the concept of good practises on decommissioning of technology. This consists of helping the user to overcome the removal of pilot technology in order to find alternatives to the tested technology. This is targeted to diminish the impact of technology absence right after the pilot.

2.3.3 Netherlands

Because Philips treats ethical issues very seriously, an internal process was designed to fulfil the obligations stipulated by the Dutch law. The internal Philips process consists of two parts:

- The first part deals with ethical issues. It mimics the process used by official regulatory bodies to approve medical trials (see case (1) above), but in a lighter form.
- The second part deals with the safety of devices used in trials. This only holds for devices that have no formal CE approval, such as research prototypes. The goal of this part is to obtain the Philips internal “declaration of conformity” that confirms the safety of devices used in a trial. This “declaration of conformity” is required only for devices manufactured by Philips, and is granted (or refused) by an internal Philips committee. For other prototype devices used in a trial, Philips expects that their safety is a sole responsibility of the respective manufactures, and requires a similar “declaration of conformity” from them.

This process is based on the following rules and regulations:

- The *"Medical Research Involving Human Subjects Act"*[1] was adopted in 1998. One of the principal aims of this Act is to provide protection to subjects who take part in medical research. The Act concerns all medical research in which people are subjected to treatments or rules of behaviour. In the Netherlands, medical research involving human subjects may only be carried out if a recognized review committee has approved it. The Medical Research Involving Human Subjects Act regulates this review. Research protocols are only approved if it is reasonable to assume that:
    - The research will lead to the advancement of medical science;
    - The aforementioned advancement could not be achieved without the participation of human subjects or with a less radical intervention;
    - The risks and burden borne by the subject will be in proportion to the potential value of the research.
- The "Medical Research Involving Human Subjects Act" also provides additional legal protection for patients
    - The patient must be informed in writing about the research;
    - The patient must give written consent for participation in the research;
    - Insurance must be taken out to cover any harm to the subject caused by the research;
- Dutch Data Protection Act[2]: The most important rules for recording and using personal data have been set forth in the “Wet Bescherming Persoonsgegevens” (WBP; Dutch Data Protection Act). The WBP relates to every use - 'processing' - of personal data, from the collection of these data up to and including the destruction of personal data. The Ministry of Justice published Guidelines for personal data processors[3]. The WBP implements Directive 95/46/EC into Dutch law.
- *ISO 13485:2003* Quality management systems – Requirements for regulatory purposes
- *93/42/EEC* Medical Device Directive.
- Council Directive 93/42/EEC (14 June 1993) concerning medical devices as amended by 2007/47/EC
- *EN ISO 14971:2007:* Medical devices – Application of risk management to medical devices
- *EN ISO 14155* Clinical investigation of medical devices for human subjects
    - Part 1: general requirements
    - Part 2: clinical investigation plans

In order to get the internal (and hence external) ethical approval, research projects need to submit the following three documents to the internal ethical committee (ICBE):

[1] http://www.healthlaw.nl/index2.html
[2] http://www.dutchdpa.nl/Pages/home.aspx
[3] [http://english.justitie.nl/images/handleidingwbpuk_tcm75-28677_tcm35-15485.pdf

(1) **Design & Development Plan template:** The Design & Development plan is a document that focuses on the project specific aspects of the development of a (medical) device to be used in human or animal trials. It is not a project planning but it must give insight in the way the project is organized and how the roles and responsibilities are allocated. Especially the responsibilities with respect to Q&R issues are important in particular when a project is executed in cooperation with external partners. The documentation management system that will be used for all project documentation must also be defined in this Design & Development plan. The regulatory classification and risk class of the device that will be developed in the project must be given. The same holds for the type of research in which the device will be used, i.e. a clear statement whether the research is medical research or not.

(2) **Trial Strategy Plan template:** The Trial Strategy Plan describes all the relevant details of a (series of related) trial(s) needed to assess if the trial(s) comply with the Philips ethical and business principles. The plan must give insight in the objectives of the trial(s), the justification, the devices that will be used, the partners involved in the trial(s) and their roles and responsibilities, the strategy with respect to publication of the trial results and the Quality & Regulatory issues that have to be dealt with. Details of how a trial will be conducted will be described in the Trial protocol for which the Trail Strategy Plan serves as an input.

(3) **Initial Risk Analysis template:** The Initial Risk Analysis gives an overview of all the risks associated with a trial in which a prototype device will be tested on human participants. Because a trial and the devices that are used in a trial must be safe for the participants it is needed to know the risks and define mitigation measures such that the remaining risk is acceptable. The Initial Risk Analysis is done in the very early stage of a project, sometimes the device does not even exist yet and the exact set-up of the trial is also not known. l. This document consists of two parts:

- Part 1 is a description of the Risk Analysis Process as it can be applied in a project. “ISO 14971:2007 Medical Devices – Application of Risk management to medical devices”.
- Part 2 contains the template for the document that has to be used to report the results of the Initial Risk Analysis, a document that needs to be provided to the ICBE as part of the Ethical & Business requirements compliance review.

In addition, Appendix D. provides templates for the “information form” and the “consent form” that is used to ask for consent from the participants in the test.

3 Specific ethical requirements and good practices

As part of the minimum requirements prior to the involvement of users, the following documentation was analysed in order to be handed in during the living labs tests. This documentation specifies the free will to collaborate with the project in an anonymous way, with a drop out option at any time and the guarantee of data protection before during and after the pilot operation.

3.1 Consent Forms

Following the Panek & Zagler approach of ethics in living labs, unified criteria for consent forms was needed. These criteria set the minimum features surrounding consent forms. It was agreed that each partner had room to go further into this features in order to merge national or organizational ethical requirements. The consent form represents a materialization of legal requirements of each region and even the surpass of those for ethical criteria.

Preliminary aspects:

- The information must be written as simple as possible in order to be widely understandable.
- In some cases, the research might involve users with serious disabilities. In this case assent from guardian or tutor is mandatory.
- There should be at least two signed copies, one for the main researcher and other for the user.
- An explanation of the research accounting the institutions involved, purpose, procedures must be included explicitly.
- The opportunity to withdraw from the living lab without any consequence has to appear on the consent. This is crucial for user organizations where there is any kind of membership since it must be clear for users that the withdrawal from the project does not affect their membership or service given by the organization.
- The consent form must contain the affirmation that he/she is allowed to ask any question involving the project.
- A section on confidentiality of data and availability is only for investigative purpose. Reference to the national or European law on the subject should be made. This states that the research meets the legal requirements concerning data protection.
- This data can be rectified at any moment by the user.
- The name of the name researcher and his/her contact must be written on the form as an ultimate responsible person for inquiries.
- Each specific Consent form applied at each of the different site locations complies with the above mentioned requirements so that a common approach is generated across the sites. A copy of each of the consent forms provided together with a transcription in English at the end of this document.

3.2 Information Sheets

Due to the initial knowledge asymmetry that occurs when piloting a service in a living lab environment (Eriksson 2005) between the user and the researcher, a complete and vertebrate form sheet should be handed out to the user .This sheet must contain a complete view of the project, from partners taking part in the project to aims and

different procedures to be used. Parallel to the consent form, it should be written in simple language without many technicalities.

Information referring to a user-centric approach will stimulate the user for an active participation on the living lab since this approach sees the user as an agent of change who generates feedback. Explaining this idea might modify the distorted vision of users participating in a research “as experimental mice in an old fashioned lab”. Giving this information is also valuable for the user since he/she can be aware of what the researchers expect (with no compromise though), therefore he can see himself as a dynamic actor who is taking part of the research actively. This Sheet is attached to the consent form.

3.3 Decommissioning of Equipment

After the pilot phase is finalised in the living labs, and technology is removed from the home environment, some key ethical questions arise. Taking into account that technology is tackling an existing need; the act of removing this technology leaves the user in a complex situation. There must be a strategy designed by researchers in which those needs are at least partially compensated.

An important principle is to state clearly to the users the limitations in time and involvement in this type of pilots in the living labs, especially in real home environments, specifying that this is a research project and as such, it is limited to a certain time length regarding the testing period, upon which the services and the equipment will be removed.

A proposed approach of this strategy is shown in the following table in which the needs addressed by the robot are described together with alternative-feasible way to tackle that need partially. This Alternative can be rationalized in different operational steps. Since after the decommissioning no system will be delivered, firstly it is essential to assess what technology is available for the user on his daily life (i.e TV, Computer or Phone) and from there, start designing a simple training strategy in which all this impacts can be minimised with the use of that available technology.

ID	Need addressed	Technology Available	Alternative	steps
01	Telepresence.	Computer and Non-smart phone	Web-cam	1-Training on webcam software easy to handle
02	Fall Handling	Mobile Phone	Use of the Telecare Button/ Mobile phone programming an emergency button	2- Training on telecare protocol for fall handling and possible scenarios -Training on programming a mobile phone with an emergency key in case of emergencies.
03	Coaching	Computer, Mobile Phone	Introducing to online	3- Training on social networks

			communities of care and coaching	and online communities that can be useful for the coaching need of the user

Furthermore, following their voluntary collaboration, each of the users will be considered for future technological pilots if they wish so, giving them the opportunity to interact and experience this advantages in future collaborations.

4 Living lab task description

4.1 Background

This section describes the living settings and characteristics at each location. We see pertinent to have a grasp on the particular conditions of each site in order to have a clearer and specific view on where and how living labs conditions will affect the test to be conducted. By describing the living lab settings we can start thinking on the most suitable use cases as well as the most common functionalities. Moreover, regarding ethical requirements, the following description can identify the nature of interactions as well as potential risks associated providing useful information for the methodology and risk assessment to be included in D6.2. It is pertinent to point out that there are two different living lab frameworks, one represented by TID in which the lab is set In the actual home and the other represented by OFFIS and PHILLIPS which are recreation of houses at the organization premises.

4.2 Settings

4.2.1 Germany

The IDEAAL Living Lab (Integrated Development Environment for Ambient Assisted Living) consists of a senior apartment in the OFFIS institute building. It is a fully functional two room flat consisting of a living room, sleeping/working room, kitchen, bathroom and corridor. The apartment reproduces all areas of normal life. Beside a home automation infrastructure to demonstrate today's possibilities the Living Lab demonstrates research and development results of several AAL projects at the OFFIS institute. The realization of the IDEAAL apartment was geared to the taste of the focus group by including the opinion of an example couple.

It provides a basis for technical test in a real environment as well as feasibility and usability studies. Second it is a showroom for demonstration of ambitious and realistic usage scenarios.

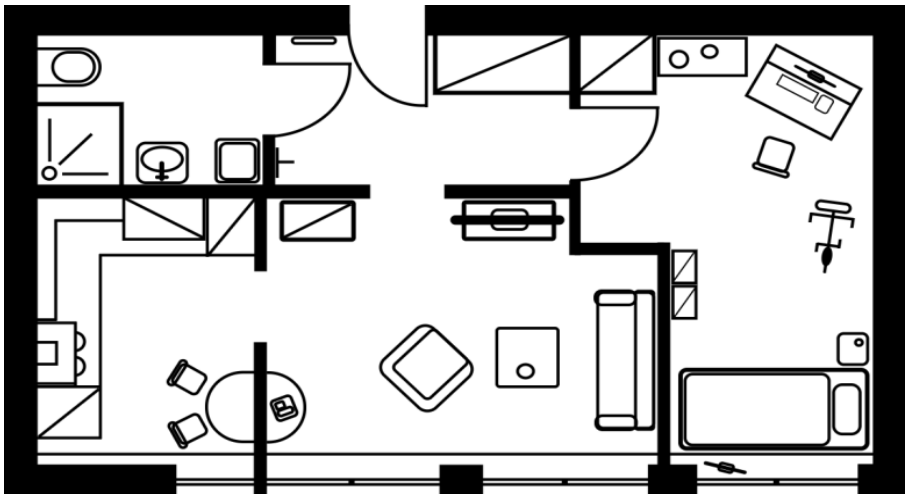

Figure 5: IDEAAL living lab

Figure 6: The living room

Figure 7: The kitchen

4.2.2 Spain

The Living Lab Salud consists of 5 sites in the home of volunteer residential customers. In the volunteer's premises, a residential gateway is installed connected to the metropolitan network by an ADSL connection, the robot will be accessed by the wireless local area network (WiFi) at home.

The profiles proposed for The Living Lab Salud it is composed of 5 customers and their caregivers (family or not) that contemplates different personal profiles and geographical , for any selected profile there will be other 2 people more with different profile (young, professional or caregiver)

Health \ Localizacion	**Granada**	**Sevilla**
Good Health	X 1	X 1
Light chronic	X 1	X 1
Some degree of impairment	X 1	-

Profiles	**Granada**	**Sevilla**
Elder 5	X 3	X 2
Young familiar 5	X 3	X 2
Coacher / Caregiver 5	X 3	X 2

The total of the profiles will be of 15 (5x3). The interaction with the users is through two DELPHI questionnaires carried out during the installation of the robot in the home of the user (or via web) and the other when the robot was collected.

Figure 2: The Living Lab Granada are real users in real homes, conceptual foto.

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4.2.3 The Netherlands

The Philips Home lab is a permanent fully functional home laboratory built to study how people interact with prototypes of intelligent technology in a real-world environment. Through Home Lab, Philips researchers can better understand their needs and motivations to use technology, and bring better products to market in the quickest possible timeframe.

The Philips Home Lab is built as a two-storey house with a living, a kitchen, two bedrooms, a bathroom and a study. The observation room adjacent to the “home” has a direct view into the Home. Signals captured by the cameras can be monitored on any of the four observation stations. Each observation station is equipped with two monitors and one desktop computer to control the cameras and to mark observed events.

The pictures below show the observation room and the living room. The Philips home lab is part of the Philips Experience Labs. In addition to the home lab the Experience Labs consist of a shop lab, a care lab and a hospitality lab.

Figure 3 Overview of the control room

Figure 4 Overview of the Living room in the Philips Homelab

5 Conclusions

In regard to the information and steps provided in the above described sections, the consideration of the regulatory and ethical issues within Florence Project is considered to be solid and reliable in respect of the scope and general requirements during the pilot phase, specially having regard to the nature of the services to be provided and the legal implications addressed along this deliverable from the national regulations and ethical requirements perspective. Further specific risks assessment and identification of the use cases to be piloted at each of the living labs will be provided along with the methodology in D6.2.

All ethical and legal issues addressed in this document are presented not just theoretically, but more importantly pragmatically. The culmination of this deliverable is the consent forms and information sheets that are going to be handed out and signed by users.

As it was seen in the description of each living lab, they are not really identical since some of them take place in real environments and others in prepared settings. That is the reason why a common ethical and legal ground had to be found in order to unify aspects and features. Other differences have been found regarding each national requirement which were added to the specific setting at each of the site, but that in general still cover a common methodological approach in terms of minimal requirements across the sites.

In the end, a unified criterion has been produced to serve as a main guideline when preparing the documents. Finally, the basic message is that these legal documents do not only intend to avoid and state legal responsibility but also to set good practises and ethical integration of users in innovation projects and more specifically in the Florence Project.

6 Bibliography

Almirall, E. & Wareham, J. (2008) 'Living Labs and Open Innovation: Roles and Applicability', The Electronic Journal for Virtual Organizations and Networks, Vol. 10, pp. 21–46

Almirall, E. & Wareham, J. (2009) 'Contributions of Living Labs in reducing Market Based Risk', *15th International Conference on Concurrent Enterprising (ICE 2009)*, Leiden, The Netherlands, 22–24 June 2009

Bohn, J., Coroamă, V., Langheinrich, M., Mattern, F., & Rohs, M. (2004) 'Living in a World of Smart Everyday Objects – Social, Economic, and Ethical Implications', Human and Ecological Risk Assessment, Vol. 10, pp. 763–785

Chesbrough, H.W. (2003) *Open Innovation: The New Imperative for Creating And Profiting from Technology*, Boston, Harvard Business School Press

Eriksson, M., Niitamo, V.-P. & Kulkki, S. (2005) State-of-the-art in utilizing Living Labs approach to user-centric ICT innovation – a European approach, Lulea, Sweden, Center for Distance-spanning Technology, Lulea University of Technology

European Commission [EC] (2009), Living Labs for user-driven open innovation: An overview of the Living Labs methodology, activities and achievements, Brussels, European Commission, Information Society and Media

Galbraith, B., Mulvenna, M., Martin, S., & McGloin, E. (2008) 'Living Labs: Helping to Meet the Needs of Ageing People?' in *Aging, Disability and Independence: Selected Papers from the Fourth International Conference on Aging, Disability and Independence (ICADI 2008)*, St. Petersburg, FL, 21–23 February 2008, pp. 105–118

Kviselius, N. Z., Ozan, H., Edenius, M. & Andersson, P. (2008) 'The Evolution of Living Labs – Propositions for Improved Design and Further Research' in *Proceedings of the 5th International Conference on Innovation and Management (ICIM 2008)*, Maastricht, The Netherlands, 10–11 December 2008, pp. 842–856

Santoro, R., & Conte, R. (2009) 'Living Labs in Open Innovation Functional Regions', *15th International Conference on Concurrent Engineering (ICE 2009)*, Leiden, The Netherlands, 22–24 June 2009

Schumacher, J., & Feurstein, K. (2007) 'Living Labs – the user as co-creator', 13th International Conference on Concurrent Enterprising (ICE 2007), Sophia-Antipolis, France, 04–06 June 2007

7 Appendixes

7.1 Appendix A: INFORMATION FOR STUDY "CONTROLLED HOME ENVIRONMENT TESTS FLORENCE" PHILLIPS

Template Information Letter for volunteers and Informed Consent Form

INFORMATION FOR VOLUNTEERS
< name of the research project >

INFORMATION LETTER FOR VOLUNTEERS IN THE PROJECT

< full name of the project as it is also on the trial protocol >

Invitation

Dear sir/madam,

We kindly ask you if you are willing to participate as a volunteer in a research project. In this information letter we inform you about this project because before you decide whether you want to participate or not, it is of course very important that you understand why this research project is conducted and how it will be conducted. Please take time to read this information and if you like discuss it with others.

Contact the responsible investigator if there is something that you do not understand or if you need more information. Names and addresses can be found elsewhere in this document.

Please take sufficient time to consider your participation.
Thank you very much for reading this information and for considering your participation.

<name and contact data of responsible researcher>

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INFORMATION FOR VOLUNTEERS
< name of the research project >

What is the goal of this research project?

<Describe the primary goal and optionally the secondary goal of this project as it is also described in the trial protocol>
Data that are gathered during the project will also be used in scientific publications, presentations or reports.

Where will the research project be conducted?

The research project will be conducted in the Philips premises on the High Tech Campus in Eindhoven.
If you decide to participate the responsible researcher will inform you about where en when you have to report for the experiments.

Who organized and paid for the research project?

This research project is organized and paid for by Philips Research. The information that is gathered in this project will be used to develop new products or to improve existing products.
Philips Research has carefully prepared this project and the set up has been reviewed by an independent internal review committee. Special attention has been given to the safety of the devices that will be used in the project.

Who are involved in this project?

The research project will be conducted by

Responsible researcher	<name and full address of the study manager>
Cooperating researchers	<list of all names and addresses of investigators>
Independent medical advisor (Only if applicable!!)	<name and address of the independent physician>

In total about <...> volunteers will participate in this research project.

Duration of the project

If you decide to participate the total time of your participation will be about <....> hours, starting from the moment that you have signed the informed consent form. During the project you will be asked to visit the location where the project will take place <...> times.

What are the steps in the research project and what is expected from me?

<Describe in a very general way the various steps in the project in which the volunteer is involved (e.g. intake, n experiments, exit discussion, questionnaire) and describe what you expect from the volunteer. A schematic overview, with time lines (e.g. intake in week 1, experiments in week 2, 4 and 7, etc.) helps to clarify.>

INFORMATION FOR VOLUNTEERS
< name of the research project >

Which equipment will be used in this research project?

<Give a description of all the equipment that will be used in this project. If possible drawings of photographs should be used to clarify.

Clearly indicate the regulatory status of all devices that will be used (CE/FDA approved or research prototype).>

Is it mandatory to participate?

Your participation is absolutely voluntarily. If you decide to participate you will be asked to sign the informed consent form on which you state that your participation is indeed voluntarily. This form will also be signed by the responsible researcher who will conduct the experiment. You will receive a copy of the informed consent form and this information letter for you own use.

Can I stop my participation?

Your participation in the research project can stop for several reasons:
You decide to stop. That can be at any moment. The responsible researcher will ask why you decide to stop but you are entitled to refuse giving an answer.
The responsible researcher decides that you can no longer participate because:

- further participation may cause harm to you
- you did not comply with the instructions for participation that were given to you
- you do no longer comply with the criteria for participation
- Philips Research decided to stop the research project

If your participation is no longer possible, the responsible researcher will inform you about this.
Please note, in case your participation stops personal data already collected about you will be further processed by Phillips as described in this information leaflet, however, you always have the right to have it deleted if you wish so.

Can I participate when I am pregnant or breast feeding a baby?

<Two different situations are possible:
The project focuses explicitly on women that are pregnant or breast feeding.
The project has no special focus on women that are pregnant or breast feeding.
The text that can be used is different in these two cases.
>
<Text in case 1>
This research project focuses on women that are pregnant or breast feeding. Philips Research has made sure that the equipment that will be used in the project and also the set up of the experiment is such that it will not have any negative impact on you and your (unborn) child.
<Text in case 2>
Because we do not know if the procedure that will be used in the experiment and/or the (medical) device that is being tested in this research project has any impact on your unborn baby or infant, participation in this project is not allowed when you are pregnant or breast feeding a baby.

What happens if I get pregnant?

If you get pregnant when you are still participating in the research project you have to stop your participation. You do not have to inform the responsible researcher if you not want to do so. If you decide to inform the responsible researcher she/he will exclude you from further participation.

What are the potential risks of participating in the research project?

<Describe the risks for the volunteer that are associated with participation in this research project>

What are the benefits of participating in the research project?

<Describe the benefits for the volunteer if he/she participates in the research project. If there are not real benefits then this should also be clearly stated. Make very clear that even if there are no personal benefits the participation in the project will allow the development of (new) (medical) devices that may help others in the future.

Add a consideration that shows that in the view of the research team the benefits outweigh the risks.>

Insurance

According to legal obligations Royal Philips Electronics has arranged insurance for all volunteers that participate in the research project. The insurance covers all damages that are directly related to experiments that are conducted in the research project. It covers all damages that become apparent during the research project or during 4 years after the end of the project. Damages need to be reported directly to the insurance broker. However, we kindly ask you to report your damages also to the responsible researcher.

The insurance agent is:
Name
Address

Tel.
Policy number

The insurance covers personal damage to a maximum of €
A number of damages are excluded. There is no coverage in case of:

- Damage from which it could almost be predicted that is would occur because it is very inherent to the type of research project;
- Damage that would have occurred also when you would not have participated as a volunteer;
- Damage caused by not adhering to the instructions given by the responsible researcher.

A detailed overview is given on the insurance policy. If you like this can be obtained via the responsible researcher.

Questions and additional information that you may need

You have the right to ask questions or additional information at any time during the research project (before, during or after your participation).
If an independent medical adviser is assigned to the project you can contact him/her. But you may also contact the responsible researcher to get the additional information that you like to have.

Compensation

<Describe the compensation the volunteers will receive as a reward for their participation. Clearly indicate when the compensation will be given and do not forget how you will deal with the compensation for the volunteers that either decide to stop themselves or have been excluded by the responsible researcher.>

Will my participation be kept confidential?

Your identity and your participation in this research project will be kept strictly confidential. Philips is committed to respect the right of privacy.

If you decide to participate in the research project your personal data will be collected during the experiments. The personal data to be collected may be related to your health, ethnical background, sex life or other sensitive aspects. In order to protect your privacy the following process will be applied: All your directly identifying personal data (e.g. name, address, ...) will be separated from the research data (e.g. your measurement data) and replaced by an assigned number/code. The directly identifying data will be only used to contact you. Access to the key/link between the assigned number/code and your identity will be limited to the responsible researcher and might only be disclosed to regulatory authorities or ethical committees that approve and monitor this study, if required for reporting to the these; or to the independent medical advisor in case of medical need.
In case any directly identifying data cannot be removed and coded as indicated above due to reporting requirements or due to technical limitations, the responsible researcher will inform you about the personal data that will not be coded and also why this will not be done.
The research data will only be used for research and development purposes, including, but not limited to, to draw conclusions about the [medical] devices that are used in the project. However, the research data might be also used for other research and development purposes than those of this project.

Due to regulatory requirements your personal data will be stored at least for 5 years. During this time you have the right to request an overview of my personal data that have been collected about me and can have it corrected or deleted. To do so, you can contact the responsible researcher.

What happens if relevant information about my health status is found during the research project?

It is of course possible that during the research project some information is found with respect to your medical condition that you were not aware of. If this happens we have to inform you about this. In the informed consent form we explicitly ask you to agree to this. If you do not want to be informed and hence do not agree you cannot participate as a volunteer in the research project.

INFORMATION FOR VOLUNTEERS
< name of the research project >

What happens with the results of this research project?

Primarily the results will be used for the development of new (medical) products or to improve existing products. It is very likely that a report will be published about this research project and that the results will be published in scientific magazines presented or presented in scientific conferences. It may be that that the data will be used in the future for the development of other products. Your identity will always be kept confidential.

Thank you very much for reading this information letter en for considering your participation in the research project.

If you decide to participate you will get a copy of this information letter and a copy of the signed informed consent.

INFORMED CONSENT <Full name of the project >

Volunteer

- √ I have read and understood the information letter about this research project and all my questions have been answered by the responsible researcher
- √ I had sufficient time to consider my participation in this project and I am fully aware that my participation in this project is voluntarily.
- √ I know that I can decide not to participate of stop my participation at any time without giving any reason for this decision.
- √ I understand and agree that my personal data will be collected, used and processed, for the purposes of the research project, by the responsible researcher and other parties that are involved in the research project. The personal data to be collected may be related to my health, ethnical background, sex life or other sensitive aspects. I understood that my directly identifying personal data (e.g. name, address) will be separated from the research data and replaced by an assigned number/code. Access to the key/link between the assigned number and my identity will be limited to the responsible researcher and might only be disclosed to regulatory authorities or ethical committees if required for reporting to the these; or to the independent medical advisor in case of medical need.
- √ I agree to the use of my personal data for other research and development purposes.
- √ I know that I have the right to request an overview of my personal data that have been collected about me and can have it corrected or deleted..
- √ I have received a copy of the information letter that includes the description of *<name of the device that will be tested in the research project>*.
- √ I agree that I will be informed about findings related to my medical condition that are detected during the research project.
- √ I understood that any and all information related to the study, including, but not limited to, information brochures, study descriptions, prototypes, user manuals, instructions as well as information generated by myself during the study, e.g. measurement results, user feedback constitutes confidential information of Philips. I hereby agree to keep the aforesaid information confidential, use it exclusively for the purpose of my participation in the study and not to disclose such information to any third party.

INFORMED CONSENT

√ I agree to participate as a volunteer in this research project.

Name	Signature	Date

Responsible researcher
I have answered all questions about the research project and discussed the meaning and scope of this informed consent and signed it in the presence of the volunteer.

Name	Signature	Date

7.2 Appendix B - Information for study "Controlled Home Environment Tests Florence" OFFIS

Dear Participant!

We'd like to thank you for your participation in this study. This study is part of the research project "Florence" funded by the European Union during the seventh framework programme.

The aim of the Florence project is to improve the well-being of elderly (and that of their beloved ones) as well as improve the efficiency in care through Ambient Assisted Living (AAL) services, supported by a general-purpose mobile robot platform. The Florence project will investigate the use of such robots in delivering new kinds of AAL services to elderly persons and their care providers. Florence will put the robot as the connecting element between several stand alone AAL services in a living environment as well as between the AAL services and the elderly person. Through these care, coaching and connectedness services, supported by Florence, the elderly will remain much longer independent. This study will support the development of the Florence system.

This study is a test in a controlled home environment. This means that you will be able to test the functionality of the developed prototype and give feedback to the developers. During the complete test period you will be accompanied by a supervisor to answer questions or help in case of technical problems. So you will test the system and we will collect the feedback of the use of the system.

During the study data will be collected. This includes an audio recording of your comments, data about the activities (e.g. duration of the talk) as well as common (e.g. age and sex) and further relevant (e.g. technical career) personal data. Also video recordings can be made. Those audio and video recordings are only used for analyzing the tests. Third party persons will never get access to this data.

Summaries of collected data (averaged over all participants) will be made anonymous before any (e.g. scientific) publication of results. Media like photos, videos or audio which may allow to recognize you personally will only be published with additional approval by yourself.

You can leave the study at any time and without giving any reasons. If you have any further questions, feel free to ask, we're looking forward to do so.

Thank you again for spending your time and effort to support the development within the medical devices group of OFFIS!

Informed Consent for study „Controlled Home Environment Tests Florence“

1) I agree to participate in this study.

2) I was told about the goals of the study. I have sufficient information about the study and the project.

3) I was told that,

   a. audio-/video recordings and written minutes are made during the study.

   b. I can deny answering any question of the study.

   c. all personal information are covered by the Bundesdatenschutzgesetz (German law of data privacy and security) so my identity will never be published without my approval.

   d. all collected data will be made anonymous before being used in scientific publications.

   e. I can withdraw my participation in the study without giving any reasons at any time.

4) I can ask Melvin Isken or Hannah Baumgartner if I have any questions about the study, the project or my participation in this study.

Participant name _____
Oldenburg, date _____
Signature participant _____
Signature investigator _____

7.3 Appendix C- Information for study "Controlled Home Environment Tests Florence" Telefónica I+D

"**Compliance with the LOPD**:

For their tranquillity and security is to inform you that, in accordance with the provisions of the Organic Law 15/1999, December 13, personal data obtained from the questionnaires shall be collected in a temporary file containing information exclusively social and in no case clinical data. This file, which has as its purpose the realization of statistics needed for the achievement of the objectives of the project Florence, accounts with the necessary safety measures to ensure full data security.

In any case, the signing of this document implies that the applicant is informed and gives its consent to the treatment of your personal data for the purpose described within the framework of the project Florence.

Please be advised that the personal data will be stored for one month after the completion of the project Florence, after which they will destroy the fields that relate the people with their answers with the statistics completely anonymous."

Florence

INFORMATION SHEET & CONSENT FORM

As a participant in Florence Living Lab, we have developed this simple fact sheet in order to introduce in the simple dynamics of a living lab and pilot while talking about what we're going to want to converse.

Florence Project

The Florence project's main objective is to improve the welfare of older people and their relatives / carers, and to improve the efficiency of care through new technologies integrated into the environment of the user.

The Florence system, with its multi-purpose mobile robot platform, it will pioneer the use of robots as well as providing new types of services for the elder people and their autonomies and their care-givers peace of mind. The main objective is to make this concept acceptable to users and profitable for society.

The project involves the integration of robots with the following features and utilities, in order to enable communication swiftly and easily between the user and your family:

- Exchange messages, photos, videos, ect.
- Communication via video-phone.
- The robot can be sent to different rooms to see if all goes well through the camera, so you have a monitoring role (to provide greater security to the user).
- Intervention at critical moments. For example, it can detect a fall and immediately implement all emergency protocol.
- Advice on training and welfare activities.
- video conferencing system that can give a "diagnosis" from the history that has in its memory, which can facilitate the work of health professionals to act in an emergency.

The identities of each participant are kept jealously under Spanish jurisdiction in privacy (protected under Law 15/1999, of protection and personal data and other related standards).

Consent Form

LIVING LAB PARTICIPATION

I Talked with…….....about the project.

It was in …….....

- ☐ I had the opportunity to discuss the project and ask questions
- ☐ I enough about the project is now
- ☐ I understand that my decision to be part of it or not
- ☐ I understand that if I want to be part of it or decide to quit, it will not affect the assistance I am receiving
- ☐ I understand that the interview may be recorded. I can stop this at any time. I have been informed that personal data shall enjoy previstal security measures in 15/1999 Law on the protection of personal data, and related regulations.

I agree to take part in the project

Signed…….....……Date……..

Name (Block letters)…….....….....

Signed (Researcher)…….....…Date……..

Name (Block letters)…….....……..