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SENIOR-TV

PROVIDING ICT-BASED FORMAL AND INFORMAL CARE AT HOME

Deliverable D5.1
Ethical Issues & Data Protection Plan

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Table of Contents

1. **INTRODUCTION**

This document represents D5.1 containing guidelines to ensure that all partners respect the ethical guidelines and data protection. It is also responsible for the delivery of D5.5 containing measures to minimize the possible discomfort experienced by the voluntary end-users at the end of the project.

2. BACKGROUND

2.1 Concerns on Ambient Assisted Living

Smart assistive technology can provide golden answers to the challenges of population aging. AAL applications can help old people to preserve or improve their physical mobility and mental agility, and to accomplish their activities of daily living. It can also improve their health monitoring, maintain them active and socially inserted, and can increase safety indoors as well as outdoors for elderly persons. The UN International Plan of Action on Ageing (Madrid 2002) states the development of supportive environments and Assistive Technology (AT) as its 3rd Priority Direction - Ensuring Enabling and Supportive Environments.(1) Among the United Nations Principles for Older Persons, those of Independence ("older persons should be able to live in environments that are safe and adaptable to personal preferences and changing capacities"), Care ("older persons should have access to social and legal services to enhance their autonomy, protection and care"), and Dignity ("older persons should be treated fairly regardless of age, gender, racial or ethnic background, disability or other status …") are closely touching Ambient Intelligence and AAL developments. Based on the basic pillars of the WHO concept on Active Ageing (2), the specific needs of older people should be classified into six groups: physical and mental health, safety, independence, mobility and general social interaction, participation and intimacy. It is expected that due to better information, in the near future the older people will be more proactive in seeking AAL applications able to support their needs from each of these categories and improve their quality of life.

2.2. Classic geriatric health providers and AAL applications

It was documented that the care provided by an interdisciplinary team results in better clinical outcomes and higher satisfaction of the patient [3]. In exploring such new, "shared care" models of health care delivery the involvement of AAL applications may add real value to the long-term care giving. The requirements for demand - complex services is estimated to grow in the coming years, so that "the use of smart home technology to support independent living is hereby inevitable" [4]. However, their implementation can be difficult because of their costs that might be too big for the health insurance companies. Another possible barrier should be the reluctance of old people to more or less sophisticated smart devices. Among the studies that investigated the compliance of old users with various disabilities to video-based smart home care solutions, that of Ziefle M and Holzinger A (2011) points out that users' acceptance, needs and wants must be seriously considered in the design of new smart assistive technologies (5). Other authors consider that due to the more and more frequent exposure to computer applications the old people of tomorrow will be more open and increasingly competent in using smart technological innovations. However, not all elderlies will be able to take advantage of these technological advances. The "digital divide" will persist, due to a significant variability of their educational background and experience with smart technology [6].

2.3 European geriatric care and smart assistive technology

In the more industrialized European countries life expectancies are higher, families are smaller, and the "young" are sometimes middle-aged. The majority of the elderly are living alone (8). Older people in need of full time care are estimated at 5% for the age group 65-69 years, 10% for the 70-79 age group, and 30% for the group aged 80 and over (9). The care of chronic and disabled patients involves lifelong treatment under expert supervision. Home Care has been considered as a fundamental component of long term care, capable of reducing expenses, institutionalization and risk of death. Ambient Intelligence (AmI) is envisaged as a major component of home care, but AmI platforms as constituent parts may be provided by different manufacturers and need to be made compatible with each other. Standardization may reduce the cost of AmI systems. ISO (International Standardization Organization) and International Electro Technical Commission (IEC) have together produced the ISO/IEC Guide 71:2001: Guidelines for standards developers to address the needs of older persons and persons with disabilities. The ISO/IEC Joint Technical Committee One (JTC1) issued ISO/IEC JTC 1/SC 35; User Interfaces and ISO/IEC JTC1 SC36; Information Technology for Learning, Education, and Training (10).

By the highly innovative solutions that it may provide, AAL technology meets "the new paradigm on ageing" promoted by the most recent European programmatic document – the Strategic Plan of the European Innovation Partnership on Active and Healthy Aging – EIP-AHA 2011. (11) This new paradigm includes among other the development of personalized, dynamic and sustainable care services. According to the third pillar of the Strategic Plan – the Active Ageing and Independent Living – the "deployment of innovative approaches and solutions, including those enabled by social innovation and by ICT can facilitate change of current practices and better deliver the desired results. Social innovations and new ways of organizing society around independent living for older people can be strengthened by wider use of innovative ICT solutions." The document also points out that "for being interoperable, scalable and ensure 'buy-in' of the end users, the technical solutions for active independent living still need to overcome a number of barriers, such as limited standardization, complex procurement procedures and limited involvement of users in the innovation process." (11) At the same time, the use of ICT raises challenging ethical issues.

3. ETHICAL ASPECTS REGARDING ADVANCED TECHNOLOGY FOR OLD OR FRAIL PEOPLE

The Annex 3 of Guidelines for ethical considerations in the projects cofounded by the Ambient Assisted Living Joint Programme (AAL-JP) specifies that the ethical issues pursue two distinct categories:

- issues related to the implementation of the project, and
- issues related to the solutions adopted in the project. (16)

Both must apply the national and international ethical rules specific for end-users and to society in general, from the concept phase to test installations and eventually launching in the market. It is pointed out that the nature of AAL projects raises a broad range of ethical concerns, most of them related to the technology involved that is often unfamiliar to the end-users and being sufficiently complex to not allow a full transparency for end-users and other stakeholders (privacy, control of personal data, confidentiality,

autonomy and dignity). The solutions developed must be trusted, accessible and accepted by all user groups involved in the project, and must address the relationships and social networks of the involved and eventually future end-users. Ethical rules in AAL projects concern end-users recruitment and, their participation in the project development process, the informed consent as a standard procedure, the protocol of their participation in prototypes testing and validation, and the precise information on how the end users can withdraw from the project at any time and the possible compensations provided to them for participating (expenses or fees paid, etc.), the possibility to contact a person in their own country for ethical issues and related questions. The exit rights for individual end-users (withdrawal from the project at any time, without giving a reason and without incurring costs or penalties) must be clearly specified and carefully managed because termination of the project may create problems in the terms of losing a help they got accustomed with. Other important issues that require ethical awareness are information and data management, the storage and transmission of personally identifiable information, the application of the national rules of the involved partners, the statement or permission by national and partner institution ethical committees, and the macro level distributive ethics (justice, equality of access, choice etc.). Of a great importance and help in the ethical management is the permanent communication with the National Contact Point.

In the Internet Encyclopedia of Philosophy the field of ethics includes concepts of right and wrong behavior systematization, defending and recommendation (12). In the field of AAL, ethics supposes what the specific stakeholders 'should' do as the right thing for primary and the other categories of users.

Quoting the definition of Ethics advanced by G. Hermerén as being the "result of our pursuit to systematically reflect on, analyze, and question the norms and values that guide human action", I. Borges (13) points out that "there is a very fine line between technology that promotes independence and technology that threatens individual freedom". The actual development of assistive technology must carefully consider the moral and ethical issues related to its use, especially the key ethical principles able to avoid the compromise of the basic human rights: end-user autonomy and consent, safety and independence, balance between avoiding harm and respecting decisions, privacy protection, dignity, integrity and preferences, treating the individuals fairly and equally. The most important approach lies in the concept of "human centred design approach" (13), meaning that end users must be involved in the technological research process and design. Other operant issues are the creation of user's feel of ownership, acceptance (human-machine compliance), choice, and freedom to "opt out" at his/her own convenience, as well as the creation of legal frameworks able to guarantee the involvement of fragile or mentally disabled people. Another critical non-discriminative item is the equal economical accessibility of old or frail people at need and the need of developing specific socioeconomic studies, promoted including from governmental level.

In accordance with the "*ICT for elderly people, Final report from the consensus conference of The Norwegian Board of Technology (2000)*", "the introduction of information technology may reinforce existing problems and dilemmas, at the same time as it may involve improvements for each individual in need of nursing. Clarification of the ethical aspects is therefore vital". Also, the Report points out that "for decision-makers in state and local authorities the saving of economic means by introducing ICT in welfare services may be an important motivation. This is understandable and not necessarily unethical. However, when the introduction of information technology reduces the quality of welfare services, the matter is different. Technology is not a substitute of care and human contact" (14). Rather, these technologies are to be regarded as a necessary complement.

S. Rogerson proposes three ethical perspectives in smart assistive technologies development: The Utilitarian perspective, the Aristotelian, and the Kantian one (15). The utilitarian principles include utility ("ethically good" means provided benefit, "ethically bad" means harming), equality (treating everyone equally), and overall utilitarian strategy (the most benefit and the least harm). Essential "utilitarian" questions may be:

- How can support and opportunity be equality achieved?
- Should equality for all be the default startup of the product?
- How can affordability be achieved?
- What are the obligations regarding affordability of ICT applications and whose obligations are they? (15)

Inside the Aristotelian ethical perspective (raising citizens who regularly adopt courage, integrity, reliability, responsibility, prudence, temperance, justness, persistence etc.), Rogers formulates several key questions:

- "How are self-determination and risk taking by the elderly incompatible with current e-inclusion thinking?
- In order to promote self-determination, how are all citizens involved in the development of e-services that promote social inclusion?
- Is it acceptable that assistive technologies that exceed human abilities are developed and in particular for those people with disabilities?
- Is it defensible that those people who, for whatever reason, have no or limited access to on-line services are disadvantaged?
- To what extent are on-line government services perceived as untrustworthy by disaffected groups?
- What is the balance between sustaining individual privacy and promoting e-inclusion?
- What is the balance between sustaining individual privacy and promoting e-inclusion? (15).

Finally, there are several important questions issued by S. Rogers inside the Kantian ethical perspective (worth in him/her and "in charge of their own lives and actions"):

- "How can government on-line services be implemented in a way that respects the EU as a heterogeneous population in terms of culture, economic prosperity and age?
- How can public access points to on-line government be de-stigmatized?
- How can the design of human interfaces for smart environments ensure people with sensorial, physical or cognitive restrictions are treated with worth and dignity?
- In order to promote ICT acceptance and effectiveness, how can respect for cultural diversity be realized in generalized ICT products and services?
- In order to treat people with dignity, how can e-inclusion initiatives cater for changing requirements and preferences as people get older?
- Regarding e-inclusions what is special about informed consent for people with disabilities?
- What is important about an individual's autonomy and dignity when planning e-inclusion initiatives?"

A comprehensive review of the ethical issues related to research and practice of smart assistive technology for frail and disabled elderly in Europe is provided by the CARE Project in its *Report on Ethical Considerations of the Design and Implementation of CARE* (17). The Report investigates the technology related ethical aspects, EU legislation background regarding ethical issues, overviews the European organizations acting in the field of ethics and provides ethical guidelines for research and deployment phases related to the CARE project. The ethical framework has to deal with rules to be applied in order to act right: consequentialism (the action that is likely to provide more benefits is the right one), Kantian ethics, autonomy, beneficence (non-maleficence), justice, distributive ethics, affordability, age-friendly design and the ethical approach of intergenerational solidarity.

CARE project Report also signals the importance of the opinion of The European Group on Ethics in Science and New Technologies' on Ethical Issues of Healthcare in the Information Society (1999, Opinion 13) and its content: "the pervasiveness of a technology that many people do not understand; the lack of transparency that may be brought to the work of healthcare professionals and its effects on the doctor/patient relationship; the difficulty in respecting privacy and confidentiality when third parties may have a strong interest in getting access to electronically recorded and stored personal health data; the difficulty in ensuring the security of shared personal health data; the lack of adequate infrastructure in certain regions and the absence of computer literacy in certain sections of the population, which may reinforce existing inequalities". Contextual dimensions such as culture, TIC literacy degree, adaptability to certain types and components of technology are equally connected to the important ethical principle of beneficence (non-maleficence). In the CARE Project, the elaborated user needs and requirements interview and questionnaire for end-users, caretakers and other stakeholders were reviewed and approved by The Budapest University of Technology and by the Economics Behavioral and Biomedical Institutional Review Board (17).

European and international laws, rules and regulations

Various European and international laws, rules and regulations on human rights are able to provide important guides for smart assistive technology development.

Human rights (civil, political, cultural, economic, the right to liberty and free expression, equality before the law) are the obligatory background of frail and disabled people care and their assistance by means of smart technology. *The Universal Declaration of Human Rights* adopted by the general Assembly of the United Nations in 1948 and *The European Union Charter of Fundamental Rights*, adopted in 2000, are fundamental guiding marks in this respect. Their provisions related to the right of elderly to dignity, independence, privacy, non-discrimination (insertion in the social and cultural life, access to medical preventive, treatment, and recovery care), personal (data) protection, are especially tangent to the development of smart assistive technology (17, 18, 19).

The European Convention on Human Rights and Biomedicine (20) also contains provisions important for the research and practical aspects of AAL applications development such as primacy of the human being (of its interest and welfare that must prevail over the sole interest of society or science) (Article 2), equitable access to health care of appropriate quality and the concern for specific measure to be taken (Article 3), and the issue of professional standards (Article 4). Chapter III of the Convention refers to the private life right and right to information.

The EU Directive on Clinical Trials (2001) requires Member States to elaborate a system of ethical provisions and the implementation of good clinical practice in the conduct of research (clinical trials) that involves human subjects (21). The Directive does not apply to non-interventional trials (clinical development program of new pharmaceutics) (22), but in the Article 1 states that "good clinical practice is a set of internationally recognized ethical and scientific quality requirements which must be observed for designing, conducting, recording and reporting clinical trials that involve the participation of human subjects. Compliance with this good practice provides assurance that the rights, safety and well-being of trial subjects are protected, and that the results of the clinical trials are credible. The principles of good clinical practice and detailed guidelines in line with those principles shall be adopted and, if necessary, revised to take account of technical and scientific progress in accordance with the procedure referred to in Article 21(2)."

Several European documents are addressing the issue of the protection of individuals and the handling of their personal data, an issue closely related to the research and implementation in the field of smart assistive technologies for seniors. *The Directive of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data* (Directive 95/46/EC) (23) regulates the above issues within the EU as component of EU privacy and human rights law. On 25.01.2012, the European Commission launched the *Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on the protection of individuals with regard to the processing of personal data and on the free movement of such data (General Data Protection Regulation)* (24). The European Data Protection Supervisor (EDPS), an independent supervisory authority, has the mission to stand over the keeping of privacy and data protection by the European institutions when they handle and process personal data and develop new policies, in accordance with the *REGULATION (EC) No 45/2001 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 18 December2000 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* (25).

In the context of actual ICT progress ethical and legal regulations are seriously challenging. "Rapid technological developments have brought new challenges for the protection of personal data" whose "sharing and collecting has increased dramatically. Technology allows both private companies and public authorities to make use of personal data on an unprecedented scale in order to pursue their activities." (24) Compulsory rules are elaborated in accordance with the main principles related to transparency, the right of the person to be informed that a category of its personal data is under processing and the purpose of processing, to be informed about the recipients of the data. The rules also state the person's right to access all his data under processing, the right to demand for the rectification, blocking or deletion of incomplete, inaccurate data related to her/him. The building of trust in the online environment is the key element or, in absence, a serious barrier for smart assistive applications. The mandatory ethical and legal criteria of data processing include person's consent about his/her data processing. The provisions concern the purpose of data processing and the obligations of data processors: e.g. the data have to be processed in the interest of their owner, for accomplishing a task of public interest or for the fulfillment of a contract etc. (23). The data must be processed in an adequate and not extensive way, and will not be further processed beyond the initially specified, explicit and legitimate purposes. The modality of data keeping must permit the identification of their owner only on the period necessary to accomplish the purpose for which they are collected. For longer periods, justified by statistical or scientific reasons, additional safeguarding means

must be brought. A special attention must be paid to the sensitive personal data of racial, political, philosophical religious or other order.

Equal opportunity, no discrimination and universal accessibility of people with disabilities are overviewed by Szajbely K et al. in 2007 (26). Among the measures authored by Article 13 of *Treaty of Amsterdam* there are several dealing with the non-discrimination by religion, age, disability, sexual orientation etc., and equal access to goods and services.

The Decision No. 771/2006/ of the European Parliament and of the Council (2006) established the European Year of Equal Opportunities for All 2007, "towards a just society". (27)

The European Network of Equality Bodies (EQUINET) has the mission of supporting the uniform implementation of EU anti-discrimination law and protection for victims of discrimination.

4. ETHICAL ASPECTS IN THE SENIOR TV PROJECT

This section describes the ethical aspects required by Senior TV project implementation, established in accordance with the specific national and international rules, recommendations and procedures.

4.1 Short description of the activities involving voluntary subjects (end users) conducted in the Senior TV project and their Ethical implications

The specific objectives of the project are:

1. To use Smart TV in combination with Smartphones and tablets, as main interfaces; and to use other secondary peripherals (e.g. Wii, Kinect) for certain services.

2. To identify the best technological opportunity for offering a caregiving system targeted at older adults during the first six months of the project. We will conduct research on the systems that were identified in Section 2.1, always having as a reference the technological platform SAM-TV, whose success was proven.

3. To design formal and informal caregiving services targeted at older adults that live at their own home. From the very beginning, end user associations that are part of the consortium will be involved in the identification of needs, establishing priorities for an iterative development. Secondary and tertiary end users that have demonstrated its commitment [14] to the proposal will form an integral part of the design process, facilitating its participation online in all cases where it is not possible to participate in person – the presence of partners from the same country tends to promote their involvement.

4. To design services aimed at helping older adults to keep in touch with friends, family, caregivers, and other members of the community. Thanks to the use of very simple interfaces in a familiar platform – the TV – the still existing digital gap between older adults and their relatives and caregivers will shrink (e.g. the communication via Facebook or Twitter could take place between older adults using their TVs and their grandchildren or caregivers using their smartphones).

5. To take into account the cultural and administrative diversity of Southeast Europe, in terms of systems of care for the elderly. The participation of end-user associations from countries like Cyprus, Slovenia and

Romania with the involvement of research institutions and companies with experience in this sector guarantees this fact.

According to the described project objectives, SENIOR-TV will target elderly people, a segment of the population that is not very familiar with new technologies and their fundamental rights could become unprotected. For this reason, SENIOR-TV will carefully consider the ethical aspects of the project with the aim to ensure the adequate protection of the privacy and the personal rights of the users at every moment and in every situation. This aim will not only affect the end-users participating in the project, but will also consider the ethical aspects relevant for the persons and organizations participating in the project and in general the limitations and regulations that must be applied to every project activity: research, development, testing, evaluation and dissemination.

Research and development in the SENIOR-TV project will be conducted in Spain, Netherlands, Cyprus, Slovenia and Romania. In addition, field testing and evaluation will be performed in Slovenia, Romania and Cyprus.

A summary of the plans and actions foreseen to handle the ethical aspects of the project will be presented in this document. By the term ethical we mean all these issues that concern questions about life and death, about revealing personal data, revealing diagnosis, about daily life activities, care and guidance.

An ethical code supervised by an ethical committee will be elaborated for that purpose with the participation of the members of the consortium as well as an independent evaluator, an ethical advisor (Prof. Dr. Luiza Spiru). This critical evaluation will be performed during the whole duration of the project, with a special emphasis during the phases of specification, design, testing and evaluation of the prototypes.

The ethical aspects that do affect the project are:

- Personal contact details: such as photographs, name, address, phone number, email, etc., video and audio information, will also be a subject of protection.
- Personal information on marital, living status, level of independence
- Personal preferences: with regards to media usage, entertainment, information, cultural events
- User location information: when relevant, it could also be the subject of ethical concerns.

Over the course of the project, when the system will be more developed and we can observe more specifically the possible ethical problems, the consortium will specify the necessary technological measures to protect the privacy of people interacting with the system in the formal care scenario.

4.2. Ethical issues and Personal Data collected during the focus groups and questionnaire based surveys

WP1- Design of formal and informal social care services at home

This Work Package has as its main objective to gather and define, through a careful analysis, the functional requirements for the final SENIOR-TV system — which is the input for the design to be produced by WP2. This objective encompasses the definition of informal care services (e.g. serious games, audio-visual

content, social networks, contests, life-long learning approaches) and also formal care services (e.g. communication tools).

The input of the end-users (voluntary subjects) was crucial in this work package in order to identify their preferences for the existing formal and informal care services, to profile the typical SENIOR-TV end users profile and to determine end-users need with regard to formal and informal care services.

This objective was achieved during two phases of consultations with end-user representatives:

1. Phase one: focus groups with the end users held by the end-user organization in Romania (AAIF)
2. Phase two – questionnaire based surveys organized by the three end-user organizations in three countries (Cyprus, Slovenia and Romania).

All researchers are responsible for ensuring that participants:

- are well-informed about the purpose of the research they are being asked to participate in
- understand the risks they may face as a result of being part of the research
- understand the benefits that might accrue to them as a result of participating
- feel free to make an independent decision without fear of negative consequences
- may drop out at any time during the research

1. Information for participants

Informing participants about the project and procedure will form part of the recruitment process. All prospective participants contacted will be provided with one- or half-page flyer describing the research as well as some background information about the project, explaining how the data will be used and whether the information will be kept confidential. The information sheet should be given to participants prior to the focus group and should also be given in hard copy on the day of the focus group.

2. Participant consent - All participants should sign an informed consent form.

Participants should have the opportunity to provide informed consent prior to participating in the focus group or survey.

3. Management of possible user's complaints and withdrawal request

User complaints and withdrawal requests are managed by the end user partners. Each user has the right to quit the trial at any time without stating reasons. In the informed consent, it was clarified that the rejection of participation or early withdrawal has no adverse consequences for participant.

4. Recruitment

Potential participants are contacted by phone or (preferably) in writing by post/email. At this point, the research and rationale for selecting them to participate should be properly explained. If the individual agrees to participate, this is known as 'first consent'.

5. During the focus groups

The interviewer should remind the participant(s) of the purpose of the research and why they have been selected. They should confirm the participant's(s') agreement to participate. Confidentiality should also be covered: how will the data be used and stored, and will they be named or identified in the report? Finally, the researcher must make it clear that the participant can stop the interview/leave the focus group at any time and withdraw from the research, even after they have given their consent to participate.

6. Safeguarding and disclosure issues

At the start of each focus group (even if it is a second session with a participant) the researcher/interviewer/facilitator as well as in the opening letter for the survey will explain that the data collected will remain confidential.

7. Locations

For focus groups, ideally the location would be somewhere quiet and comfortable where conversations cannot be overheard to protect the confidentiality of the participant.

8. Vulnerable people

The focus groups should respect the principles that apply when conducting qualitative research with vulnerable adults:

- written materials should be printed in large letters and the design of materials should be appropriate for the audience.
- use images or visual aids and simplified language.
- accommodate to the needs of the participant for example, participants who would prefer to write or type their answers instead of talking should be provided with a template with the questions and space for answers - so a printed version of the focus group questions, in form of a questionnaire, should always be available for all participants involved in the focus group.
- in the case of mentally ill or cognitively impaired patients, it is important to measure comprehension and develop valid tools for it, before obtaining informed consent to participate in the research study.

9. Data protection & confidentiality

- All information provided will be securely kept on a password protected computer. No names or organizations will be identified within the research process.
- Data from any focus group and quantitative survey will be kept securely and fully anonymized.
- Names and other identifying features will not be used in any reports.
- Any demographic information we collect and use will be used purely for statistical data analysis and profiling.
- Any personal and sensitive data (names, ethnicity, age, gender, marital and living status, level of independence) will not be kept with the data collected from the focus groups/surveys
- In case of video recording of the focus group, all participants consent for this specific purpose (video-recording and distribution) will be obtained before the focus group.

- Questionnaires will be anonymous and encrypted for data centralization and statistical data analysis purposes.
- PC's used for data storage and analysis will be password protected.
- In case of data sharing among project partners: only anonymous data will be shared and only via secure connections.
- Participants ID data will only be mentioned on the Informed consent forms that will be kept in a locked storage device.

4.3 Ethical issues within Pilot Testing

WP3 –SENIOR-TV at home

Through the tasks of this WP the consortium will evaluate with end users the SENIOR-TV platform. This evaluation will be carried out at the older adults' homes or in elderly care facilities, in a real environment. Results from the first two cycles will be used for further refinement and development of the system, both from a functional and technical point of view. The output from the last cycle will be crucial for the final Business Plan delivery.

This work package will carry out testing pilots of the SENIOR-TV platform and services in a real-world environment: the homes of older adults or care facilities. The iterative piloting approach will allow for transferring devices between homes in order to reduce costs. The objective is to involve 100 end-users per country, which amounts to a total number of 300 end-users throughout Europe, testing SENIOR-TV at their homes. Each piloting cycle is divided into four iterations. In each one, end-user organizations of each country will transfer the devices of SENIOR-TV between users. 25 people per country will participate in each iteration. Iterations will be two weeks long in the first cycle and one month long in the second and third cycles.

At the beginning of each activity the end-users will be thoroughly informed about the project, the application to be developed within the project, the purpose, objectives and methodology of current research to be conducted, what is expected from them and the possibility to drop out at any moment. All volunteer end users participating in research activities have to sign an informed Consent form.

The field trials with voluntary end-users will take into account the aforementioned national legislation and local regulations. In every project that supposes the involvement of human subjects, the recruitment of old voluntary end-users will be made based on previously established inclusion-exclusion criteria. Within the Pilot the end users will remain as much as possible the same along the entire duration of the project. If a new end-user recruiting becomes necessary for replacing someone who withdrew his/her participation, then the entire procedure of end-users' recruitment, including Consent Form and the other ethical matters is performed. The contact details of the principal investigator and president of the AAIF's Ethics Commission – Prof. Luiza Spiru, MD, PhD, able to solve the possible issued ethical matters, are provided to each voluntary end-user. Each investigator is trained about the legal and ethical rules to be pursued during the work sessions with the end-users.

All different pilot partners should receive approval from their local ethics committee (or relevant equivalent body) when enrolling in the research process.

Information procedure

Before participants give their consent, they should be properly informed about the project, and the pilot study. They will be informed about:

1. What they will be asked to do
2. The expected duration of their participation
3. Who will be conducting the study, whether anyone else will be present
4. Whether they will be audio- or video- recorded and what exactly will be recorded
5. A reasonable estimation of whether it will be boring, difficult, stressful etc.
6. What they should do if they wish to withdraw, with information that this is their right and won't have negative consequences, particularly on their reimbursement (if reimbursed)
7. Who will have access to their data, where and how long it will be stored, with appropriate information about anonymity and confidentiality
8. How will the results of the study be disseminated

To facilitate understanding of the research methodology and concept, several actions will be undertaken. All information about the study (not only during the recruitment process, but at all stages of the study) will be provided in formats suitable for the particular participants.

It is compulsory that all the researchers working on the pilots have previous relevant experience in working with elderly and in implementing and developing tailored conduct and strategies.

Data protection

1. Treatment of data is governed not only by professional ethics, but by the data protection legal requirements. Data protection refers to all stages of data management: collection (design of data collection methodological instruments), processing, storage, transfer.
2. Over all stages of the pilot testing and beyond, confidentiality and anonymity of participants' data must be strictly preserved. In all computer files, participants will be referred to by a code that cannot identify them.
3. All computer files should be stored only on secure equipment.
4. Particular care should be taken on security issues if files are transferred between partners for analysis. This should be undertaken using secure means and the transferred data should not include any ID.
5. Audio and video files should not be shown beyond the immediate research team unless a written agreement from the participants has been obtained prior to the registration.
6. Only anonymous data can be reported in project deliverables or in public documents. Reports should mainly include aggregate data. Should individual information be necessary (like comments from individual participants) it must be reported such as to not embarrass the individual and preserve his/her anonymity.

4.4. Management of possible user's complaints and withdrawal request

As specified including in the Informed Consent procedure, the end-user volunteer is entirely free to withdraw the study at any time, at its convenience and with no penalty. However, he is informed that the

explanation of withdraw is important for the investigators and the study, so it is up to the end-user volunteer to provide it at his/her convenience.

Any complaints made by the end-users will be addressed to the principal investigator of AAIF – Prof. Luiza Spiru, whose task is to properly address them and specify them in the study report.

The researchers involved in the preparation of evaluation trials and end-user feedback collection and analysis within each pilot site have the obligation to comply with the ethical and legal framework detailed in this D2.4 document, even after the cessation of the activity in the respective organization. [42]

4.5. The ethical team

The ethical committee will supervise all the activities with the end-users during quantitative and qualitative surveys, i.e. the accomplishment of the ethical requirements. The team will also manage the possible "exit related ethical issues" from part of the voluntary end users already acquainted with the prototype during its testing and validation. The Ethical Committee of Ana Aslan International Foundation is coordinated by Prof. Luiza Spiru, MD, PhD. Regarding the personal data protection, the AAIF is registered at the National Authority for the Supervision of Personal Data Processing.

5. THE EXIT STRATEGY

A special attention will be paid to the exit strategy.

The participating professional care organizations will offer SENIOR-TV as an operational service beyond the life time of the project.

However, when they cease to provide the services, end-user have the possibility to purchase it for a small price. Yet, we need to keep in mind that SENIOR TV is a research project, which means that there is always a certain risk involved, that the idea fails (due to various reasons). Therefore, at the beginning of the project we informed the participants who volunteer to test and validate the service that, after the project ends, it may be possible that they face some discomfort because of service discontinuation.

A special set of measures will be applied in order to manage the possible discomfort experienced by the end-user when s/he must give up the devices s/he already learned to use and the useful services provided by the Senior TV app. This set of measures will include:

- Clear information about the role, of the end-user, i.e. the expectations for him as voluntary contributor to the accomplishment of Senior TV project goals, phases and activities. During the project running, this task was accomplished in the introductory presentation of each field trial with the end-users, but it will be especially envisaged in this 2nd trial phase when the end user will work during three weeks at their own homes with the fully functional services provided by the prototype.
- During initial training session after the installation of the app at the older person's home s/he will be informed about the measures that project's team adopted for minimizing the possible discomfort experienced by him when giving up the equipment and stopping to receive the smart services:
    - The possibility to keep running the app by buying the equipment and the services for a small price,

- The possibility to withdraw his/her participation at any time during the trial phase without any repercussion,
- The possibility to solve any unwanted situation or complaint by calling or e-mailing the principal investigator of the pilot site, whose contact details will be entrusted to him/her during the initial training session after the installation of the app.

The last two items will be specified in the Informed Consent form.

- A closing seminar will be arranged at the end of the project at each piloting site, with the end-users and their relatives being invited to attend. Participants will receive a diploma of participation.

6. DATA PROTECTION PLAN FOR SENIOR-TV

6.1. Legal background

Protection of personal data is regulated at the European level by Directive 95/46/EC (51). The Directive applies to data processed automatically (e.g. a computer database of customers) and data contained in or intended to be part of non-automated filing systems (traditional paper files).

It sets up a regulatory framework aiming to strike a balance between a high level of protection for the privacy of individuals and the free movement of personal data within the European Union (EU).

The directive sets strict limits on the collection and use of personal data and demands that each member state set up an independent national body responsible for the protection of these data.

Personal data is defined as "all information on an identified or identifiable person", considering an identifiable person as anyone whose identity might be determined, directly or indirectly, in particular by means of an identification number or one to several specific elements, characteristics of his physical, physiological, mental, economic, cultural or social identity and attributes special protection to health data [51].

The European Directive on the protection of personal data contains a number of key principles which must be strictly followed. Anyone processing personal data must comply with the eight principles of good practice providing that data is:

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.
8. Not transferred to countries without adequate protection.

The Charter of Fundamental Rights of the European Union (2000/C 364/01) aims to make more visible to the Union's citizens the fundamental rights that are already enjoyed at a European level. It includes, the

protection of personal data, as well as rights in the field of bio-ethics, required by advances in information technologies and genetic engineering.

The Charter of Fundamental Rights of the European Union [52] states:

Art 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.
   a. The free and informed consent of the person concerned, according to the persons.
   b. The prohibition of eugenic practices, in particular those aiming at the selection of persons.
   c. The prohibition on making the human body and its parts as such a source of financial gain.
   d. The prohibition of the reproductive cloning of human beings.

Art. 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 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.

Art. 13: Freedom of the arts and sciences.

1. The arts and scientific research shall be free of constraint. Academic freedom shall be respected.

6.2. Personal data protection in end-user organization partners' countries (CYPRUS, SLOVENIA, ROMANIA)

"Publicly available electronic communications services over the Internet open new possibilities for users but also new risks for their personal data and privacy. In the case of public communications networks, specific legal, regulatory and technical provisions should be made in order to protect fundamental rights and freedoms of natural persons and legitimate interests of legal persons, in particular with regard to the increasing capacity for automated storage and processing of data relating to subscribers and users", specifies the Directive 2002/58/EC (44).

In accordance with this Directive the Senior TV smart application to be created will take the most appropriate technical and organizational measures for safeguarding the security of its services, if necessary in conjunction with a provider of a public communications network.

In Romania, all the organizations involved in research are under the jurisdiction of National Authority for the Supervision of Personal Data Processing (Annex 1), and the legal framework is represented by:

- Law no. 226/2009 on the organization and functioning of the official statistics in Romania
- Law no. 677/2001 on the protection of persons regarding the processing of personal data and on the free movement of such data
- Law no. 682/2001 on the ratification of the Convention for the Protection Individuals related to Automatic Processing of personal data, adopted in Strasbourg on 28.01.1981, as amended subsequent

- Confidentiality rules of statistical data- National Statistics Institute. [42]

Personal Data Protection Act (ZVOP-1), was adopted by the National Assembly of the Republic of Slovenia at its session of 15 July 2004.

In Cyprus, data protection is legislated by: Processing of Personal Data (Protection of Individuals) Law 2001.

In Slovenia, data protection is legislated by: Law on Protection of Personal Data (ZVOP-1-UPB1) in the Official Journal of the Republic of Slovenia (RS 94/2007).

6.4. SENIOR-TV General aspects regarding personal data

Methods of personal data collection:

Within SENIOR-TV activities, volunteer end-users' data will be collected during focus groups, quantitative surveys and pilot testing.

Personal data to be collected:

Socio-demographical data: age, gender, marital status, living status

Preferences for: media vehicles, information means, entertainment means

Skills: computer literacy

Sensitive data: Self evaluated physical health and level of dependency

Within the SENIOR-TV project multiple aspects of the data collection processes and methods have been examined. After studying the legislation in Europe and of each implicated country, the data protection plan presented below has been developed, covering all of the aspects cited above.

6.5. General issues concerning DATA PROTECTION PLAN

Purpose of the data protection plan: The data protection plan becomes part of the signed agreement between SENIOR-TV consortium and the investigator(s) participants in the project. All members of the research team with access to the data are bound by the contract to follow all aspects of the data protection plan.

The main aim of this plan is to prevent persons who are not signatories to the restricted data use agreement or the supplemental agreement with research staff from gaining access to the data.

The plan will cover:

- Management of both the raw data file received from the SENIOR-TV consortium as well as any copies made by the research teams, and any new data derived solely or in part from the raw data file.
- Security of computer output derived from the data.

6.5. The informed consent and self-determination in the Senior TV project

The minimum features to take into account in the design of the consent forms are listed below:

1. The information must be written as simple as possible (in a jargon free language) in order to be widely understandable.
2. In cases that the research implicates participants with serious disabilities, assent from the primary guardian or tutor is mandatory.
3. At least two signed copies must be produced; one to be kept by the main researcher and the other by the end-user.
4. A thorough description of the project, the organizations involved, the study's purpose and procedures must be provided.
5. The fact that participants are entitled to withdraw from the study at any point of time without any consequences must be explicitly made. This clarification is particularly important for organizations where membership is in effect; it must be clarified that potential withdrawal from the project will not affect participants' membership or services provided by the organization.
6. The consent form must contain the affirmation that the participant is allowed to ask any questions that he/she may have at any point during the project.
7. A section on the confidentiality of data collected and its availability for solely investigative purposes must be included. 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.
8. Personal data can be rectified at any moment by the user.
9. The name of the researcher and his/her contact details must be available on the form as an ultimate responsible person for inquiries.
10. All of the participant consent forms used in the pilot cycles in Romania, Slovenia and Cyprus must comply with the abovementioned requirements so that a common approach is followed across the sites. A copy of each of the consent forms provided together with a transcription in English at the end of this document.

6.6. Data Storage and Handling Processes

The protection of participants' privacy is a responsibility of all individuals involved in research with human participants. Privacy means that the participant can control the access to personal information; he/she decides who has access to the collected data in the future. Due to the principle of autonomy the participants have to be asked for their agreement (informed consent) before private information can be collected. It should be also ensured that all of the individuals involved in research work, understand and respect the requirement for confidentiality. The participants should be informed about the confidentiality policy that is used in the research.

Privacy plays a role at different levels:

- Hints to or specific personal information of any participant in publications.
- It should be prevented to reveal the identity of participants in research deliberately or inadvertently, without the expressed permission of the participants.
- Dissemination of data among partners.

- Access to data method of access, data formats, method of archiving (electronic and paper), including data handling, data analyses, and research communications. Offer restricted access to privacy sensitive information within the organization of the partner.
- Protection of the privacy within the organization of volunteers (employers, etc.) throughout the whole process like, communications, data exchange, presentation of findings, etc.
- Destruction of data once the purposes for which the data were obtained (and for which the consent form was signed) is over.

Workstations will be configured and used in a manner that is consistent with the security practices that will protect data against exposure, but also against tampering and loss of study data sets.

All of the computers used for data storage will be password protected. No removable storage media such as CDs or flash memory drives will be used for data storage or transfer.

Participants have to be able to control the dissemination of the collected data. The investigator is not allowed to circulate information without anonymization. This means that only relevant attributes, i.e. gender, age, etc. are retained. Another possibility is to keep the identity of the participants, but only with prior consent of those.

As already mentioned, protection of confidentiality implies informing the participants about how their data may be used (i.e. data sharing).

As databases are developed, confidentiality will become increasingly hard to maintain. Simple stripping of the participants' name and its replacement with a code is no guarantee of complete confidentiality. Therefore, no personal ID data should be collected during any kind of quantitative and qualitative research excluding participants' Informed Consent form.

6.7. Encoding and Anonymization

Information should be anonymized for protecting participant's identity.

Anonymization provides a safeguard against accidental or mischievous release of confidential information.

There are different ways in which personal data can be modified to conceal identities:

- Coded information contains information, which could readily identify people, but their identity is concealed by coding, the key to which is held by members of the research team using the information.
- Anonymized data with links to personal information is anonymized to the research team that holds it, but contains coded information, which could be used to identify people. The key to the code might be held by the custodians of a larger research database.

Unlinked anonymized data cannot be used in any way by anyone to identify individuals.

As a minimum, anonymized data must not contain any of the following, or codes for the following:

- Name, address, phone/fax. numbers, e-mail address, full postcode.
- Any identifying reference numbers.
- Photograph, video or audio files of participants

- Names of relatives/carers

Researcher and database developers should always consider – when designing studies, before passing information to others, and before publishing information – whether data contain combinations of such information that might lead to identification of individuals or very small groups. We will follow the unlinked anonymized data policy, after taking into account that SENIOR-TV may include users with identifiers like age, gender and nationality. Once anonymized, the data will not allow tracing back the participant in any way, with any analysis of the data being based on group analysis.

Data will be encoded, and anonymized using numerical codes. During trials and the development stages, the correspondence with the users list will be saved into an encrypted local database.

To avoid accidentally compromising the data, information about the data's sensitivity and any available information on participants' consent will not be stored alongside the data.

At SENIOR-TV the computing environment in which the data will be used at each of the sites, will include the following measures:

- Computing platform (PC, workstation, mainframe platform): *PC*
- Number of computers on which data will be stored: *3 (all password protected)*
- Whether personal computers used in the research project will be attached to a network or will operate independently (stand-alone): *Stand-alone computers for data collection*
- *Analysis of all collected data will be made from a single stand-alone computer (password protected)*
- Physical environment in which computer is kept (e.g., in room with public access, in room locked when not in use by research staff): *In a locked room when not in use by the researchers.*

6.8. Data Destruction

Any personal data gathered from participation in the project will be kept to a minimum. In cases that collection of sensitive information is required i.e. when it comes to train or improve a technological device relevant for the project the following measures will be followed:

- Dissociation of personal identifiable data as it was specified above.
- Destruction of paper/documents by the time the project ends.
- Erasing of electronic documents containing sensitive information by the time the project ends.

6.9. Evaluation Criteria of this Data Protection Plan

These data protection plan evaluation criteria will be followed as guidelines throughout the project and its fulfillment will be supervised, deviations from it will be minimized and appropriately justified.

A brief report, describing the fulfillment of these criteria, eventual conflicts, and how these have been solved, will be supervised by AAIF and sent to the Commission at the end of the project.

The proposed criteria that will be observed to measure the fulfillment of this evaluation plan will be the following:

- The users have been informed about the objectives of the project
- The users have given their consent to participate
- What procedures have been in place to preserve the dignity, autonomy and values (human and professional) of the end-users?
- All the data collected in the user requirements questionnaire are necessary (but also are the minimum, in order to avoid asking for non-relevant, but sensitive, information)
- For any data not initially expected or specified in the consent form, a justification for its needs has been reported to the respective ethical committees (if required).
  - This may include:
    - Video information about the users.
    - Audio information about the users.
- For any data not initially expected or specified in the consent form, additional consent forms have been provided to the users.
- Sociodemographic identification data have been dissociated from the rest of information about the users (except for when it is absolutely necessary for data analysis)
- Sociodemographic identification data have been encrypted on a separate database
- Risk of identifying users in profiles or scenarios have been minimized
- Any file exchanging personal information from the users have been encrypted.
- Scenarios show conflict with legislations about privacy and security
- For those scenarios showing conflict with legislations about privacy and security, necessary adaptations to fulfill these legislations have been carried out.
- Special procedures are planned for safeguarding the right to privacy, self-determination and other ethical issues in of end users related to technology-enabled concepts for confidential communication between the older person and informal and formal carers, service providers
- Dissemination activities performed do not allow identification of the users.

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SENIOR-TV

PROVIDING ICT-BASED FORMAL AND INFORMAL CARE AT HOME

Quality Checklist
Ethical Guide and Data Protection Plan

Peer Reviewer	
Reviewer	**Partner**
Aliki Economidou	CNTI

CRITERIA	VERIFIED
1) Conformity to Standards and Project templates	**X**
Logos (AAL, SENIOR-TV)	**X**
Project title, reference, author, version, revision, data	**X**
Mandatory statements (disclaimer)	**X**
Conformance to the standard structure required by EACEA (ex. Disclaimer, Executive summary, Acknowledgement, Introduction, page numbers, etc.)	**X**
2) Language check (typing mistakes, grammar, etc.)	**X**
3) Coherence with objectives declared in the Technical Annex	
Obj. 1: To elaborate the project's Quality Plan following well-accepted methodologies tailored to the learning domain and based on a detailed description of projects objectives, success indicators and work plan.	

Obj. 2: To monitor all project activities and provide quality control of all project results as well as recommendations for improvements and identification of best practices.	
4) Reliability of data	**X**
Information and sources well identified	**X**
Data and information are free from factual or logic errors	**X**
The analysis (if applicable) is reliable, i.e. previous studies have been sufficiently reviewed; qualitative information and quantitative data are balanced and appropriate	
5) Credibility of findings	
Findings supported by evidence based on data analysis	
Replicability of findings	
6) Validity of conclusions	**X**
Conclusions meet evaluation questions and information needs	**X**
Conclusions supported by proper evaluation findings	**X**
No conclusions missing according to the evidences presented	**X**
7) Please indicate any deviations from contractual conditions (WP objectives declared in the technical annex)	
8) Comments/Suggestions for revision	
9) Implementation of revisions/modifications suggested and explanation for eventual rejections (performed by the Responsible of the Deliverable)	
10) Deliverable accepted X YES ☐ NO	
If NO, please state reasons:	

aal-2014-171

SENIOR-TV

PROVIDING ICT-BASED FORMAL AND INFORMAL CARE AT HOME

Quality Checklist
Ethical Guide and Data Protection Plan

Peer Reviewer	
Reviewer	**Partner**
Iztok Žilavec	DUNG

CRITERIA	VERIFIED
1) Conformity to Standards and Project templates	**X**
Logos (AAL, SENIOR-TV)	**X**
Project title, reference, author, version, revision, data	**X**
Mandatory statements (disclaimer)	**X**
Conformance to the standard structure required by EACEA (ex. Disclaimer, Executive summary, Acknowledgement, Introduction, page numbers, etc.)	**X**
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If NO, please state reasons:	