Voice Controlled **Assist**ive Care and Communication Services for the Home

D1.2 – Ethical Guidelines

Project Number:	AAL-2010-3-106
Coordinator	Manfred Tscheligi CURE – Center for Usability Research & Engineering, AT
Category:	Deliverable (restricted)
Reference:	D1.2; *V 1.0; 25-01-2012*
Status:	Final (public)
Responsible:	CURE
Participants:	APHP, EURAG
Related to:	WP1: T1.4. Ethical Watch

Co-funded by the AAL Joint Programme

Abstract

This vAssist document aims on developing strategies to address ethical issues and national regulations in all project activities with active user involvement, development phases and project result dissemination. The goal of this deliverable is to describe the strategies and key principles before starting any action with active user involvement. After the approval of this document by the involved end-user organizations (APHP, EURAG) each member of the project consortium will be able to identify potential ethical, privacy and security risks and, more important, knows what to do in order to avoid or minimize ethical issues and risks.

Table of Contents

Table of Figures

Table of Tables

1 Introduction

1.1 Background

The vAssist system will support older persons, suffering from age related fine motor restrictions and/or chronic diseases by providing voice controlled (supported by graphical user interfaces) communication and tele-medical homecare services, independent from the device in use (TV, PC, mobile device).

In general, ethics, also known as moral philosophy, is a branch of philosophy that addresses questions about morality - that is, concepts such as good and evil, right and wrong, virtue and vice or justice and crime. The principal aim of an ethics review is to protect all user groups involved in research throughout the lifetime of the project and also into the development and dissemination process.

In vAssist ethics plays a major role since the project follows a user-centred design (UCD) approach. This means that active user involvement in several phases of the project will happen to gather feedback about the needs and wishes of the future end users (WP2 Requirements Specification) and to evaluate the interaction with the vAssist system in lab and real world environments (WP4 Lab and Field Trial Evaluation). Further, also actions in WP3 (Service and Device Independent Platform Development) have to follow ethical key principles since they are related to the development of the system architecture for the storage of personal and private user data. Moreover, all dissemination and exploitation activities within WP5 (Dissemination and Exploitation) have to consider ethical issues related to data privacy and anonymization and encryption strategies for user data that is collected during studies of the vAssist project.

During the vAssit project there will be evaluation studies where only primary end users (older persons) will interact with the system (e.g. for medical data input). In addition, also interaction with other persons via the system will happen (e.g. bi-directional real-time communication via telecommunication channels). In both situations privacy will be a major concern since communication and private or medical related data are very personal and sensitive information.

Since in the vAssist project personal data acquisition, storage and process are important issues the project has to accomplish A) the European and national regulatory legislation (Austria, France) in order to keep the privacy of all involved users and B) to follow ethical key principles of respect for autonomy and voluntariness, beneficence, non-maleficence and justice in all activities with active user involvement.

The fact that users are active involved in the vAssist project and system development implies that ethical questions and aspects, key principles for human research and privacy of both, the vAssist primary end users and their communication partners have to be safeguarded. Next to this, all national regulations in of the partner countries where user studies take place will have to follow their national regulations. All involved users in vAssist must have the right to be informed about the fact that data of him or her may be recorded. For this reason, vAssist must be transparent to all involved persons that interact with the system.

In the vAssist project several studies with active user involvement are planned. In the initial phase focus groups, interviews and cultural probe studies with primary (older persons) and secondary (family members/health professionals) users will be conducted in WP2 in Austria and France for gathering user needs and wishes. Further, the first low-level concepts of the system will be evaluated in Austria and France in lab environments with primary users (older persons) in WP4. Moreover, the functional high-level prototype of the vAssist system will be evaluated under real live conditions in the user homes in Austria and France involving primary and secondary users.

The way in which all ethical and data privacy and security issues may arise during these evaluation phases and studies must be specified before they take place. This means that ethical key principles such as respect for autonomy and voluntariness, beneficence, non-maleficence and justice as well as European and national legislations must be followed.

This deliverable addresses the way in which ethical issues are going to be considered during the vAssist project and in any study, evaluation or other project phase where active user involvement takes place.

1.2 Scope of the deliverable

The core of D1.2 is to create a manual that defines the ethical guidelines for the vAssist project. In this manual all ethical factors, aspects and considerations are taken into account before starting any research activities with active involvement of human individuals. The aim of this deliverable is to describe how the vAssist consortium is going to maintain security, privacy and confidentiality norms and respects the common values of respect for autonomy and voluntariness, beneficence, non-maleficence and justice throughout the whole project duration including all national regulations of the involved partner states.

The main impact of this deliverable will be in the area of studies and evaluations with active user involvement. Further, ethical considerations will also have an impact on the vAssist system design itself. This means that in order to address privacy issues also various technical actions and challenges must be accomplished (e.g. to set up passwords, code and encrypt personal data, etc.). Moreover, also WP5 (Dissemination and Exploitation) involves ethical issues that are related to safeguarding private and personal user data. Hence, this deliverable is not only related to WP2 (Requirements Specification) and WP4 (Lab and Field Trial Evaluation) but also to actions in WP3 (Service and Device Independent Platform Development) where the architecture for data storage will be developed as well as the dissemination of the project results in WP5 (Dissemination and Exploitation).

In general, it is expected that D1.2 supposes the ethical guidelines for the whole vAssist project duration to protect all involved user groups. Its main aim is to establish a general framework and manual for ethical and data privacy issues as well as to collect and integrate the legislation of the involved partner countries that held personal data from involved end users. Based on these legislations, regulations and on the data protection plan described in section 6 this deliverable focuses on the elaboration of a consolidated user protection plan for the vAssist project.

The deliverable is structured as following:

Section 1 outlines the general aim of the deliverable. Section 2 provides information about the handling of ethical issues in the vAssist project. In chapter 3anoverview about the ethical advisor, the profile of the advisor and the tasks are defined. Section 4 summarizes general ethical regulations that have to be followed when conducting research involving human beings by illustrating ethical key principles from the Framework for Research Ethics (FRE) [1], the IMIA Code of Ethics for Health Information Professionals[8], the Report on Electronic Assistive Technology (EAT)[7] and the Helsinki Declaration [6]. Chapter 5summarizes the national legislations from Austria and France and chapter 6 includes the data protection plan. In the Annex section the informed consent (IC) document and information letter are attached.

2 Handling of Ethical Issues in vAssist

The next section provides an overview on how ethical issues will be handled in vAssist starting with a characterization of Ambient Intelligence (AmI) environments, the representation of possible ethical risks of AmIsand how vAssist will handle them followed by the ethical documents for the Informed Consent form and the information letter.

2.1 Identification of Ethical Issues

Modern Ambient Assisted Living (AAL) technologies, such as the solution developed in the vAssist project, offer a broad range of possibilities and opportunities for various markets and stakeholders.

The characteristics that are inherent to ambient technologies are specified by Aarts and Marzano [4] as following:

- **Embedded:** Devices are networked and integrated into the environment
- **Context Aware:** Devices are able to recognize people and their situational context
- **Personalized:** Devices have the possibility to be tailored to individual personal needs. The service or technology can be adapted on the basis of this profile in such a manner that the service will be completely matched to the needs and preferences of a dedicated person.
- **Adaptive:** Devices are able to adapt their behavior in reaction to changes in a person's behavior over time.
- **Anticipatory:** Devices have the ability to anticipate the wishes of persons.

The following lines describe 13 risks of ambient technologies identified by Wright et al. [5] focusing on social, economic, legal, technological and ethical issues related to identity, privacy and security in Ambient Intelligence (AmI) environments. Find below a summary and short outline of the identified risks and how vAssist will deal with the possible risks. A detailed mapping of risks vs. how to be addressed in vAssist can be found in Table 1.

1. **Privacy:** It is important to be aware of the implications of AmI for private life and personal data and to take adequate social, technical, economic and legal measures to protect privacy.

   Privacy in vAssist: Privacy in vAssist will be a concern since personal data of human subjects will be recorded during various evaluation studies and for the personalization of the future vAssist system and services. Diverse coding and encryption strategies will be applied to safeguard and protect personal data of the involved human beings.

2. **Security:** Is another key challenge for a successful AmI implementation. Security issues can be depicted in the following contexts: security imposed for telework, biometrics used for authentication or identification, human factors and security, malicious attacks, security audits, back-up security measures, security risks, access control, the illusion of security and viruses.

Security in vAssist: Also security will be a concern in vAssist with a major focus on the context "access control of personal data". vAssist will strive for password strategies and personalized access control mechanisms where users decide themselves who will have access to their personal data.

3. **Identity:** Different components of identity (i.e. information related to legal identity, identification, authentication, preferences, economic and financial information) play important roles in determining the feasibility of the AmI environment.

   Identity in vAssist: The vAssist project will provide different personalization options so that individual preferences and other identity aspects can be integrated to form a general personal identity within the system and services.

4. **Trust:** The notion of trust has technical aspects as well as social, cultural and legal aspects. Trust can be raised in different contexts: Trust and confidence, lack of trust (from loss of control, unwillingness to provide some data, contextual misunderstandings) and honesty.

   Trust in vAssist: Trust in vAssist will be covered from different perspectives. During studies with active user involvement legal regulations from the involved partner countries will be followed next to general ethical key principles that define the protection of personal data. In addition written documents (Informed Consent) are applied that include basic information about the user rights and scope of the project and study. From a technical point of view encryption and password strategies will be applied to raise the trust in the security of the system.

5. **Loss of Control:** This risk of AmI stems from different factors, for instance, when there is a lack of trust on the part of the citizen/consumer in the AmI infrastructure and its components or a lack of skills on how to handle different devices (i.e. older persons). It can also emerge when the complexity level of AmI devices or services is too high and consequently does not enable users to get what they want.

   Loss of control in vAssist: In vAssist several usability and user experience studies are planned to cover the possibilities of senior persons in handling the different devices and services in use. Based on the findings adaptations to the vAssist interfaces (speech, GUI) will be done to reduce the complexity level of the provided solution to a minimum.

6. **Dependency:** This risk emerges directly from the usage of a technology by the user and the prospects (benefits and alternative solutions) for the technology. Risky situations can be seen in dependence on personalized filtering, on seamless and ubiquitous communications, on AmI systems (e.g. health monitoring and traffic management systems) and users' feeling of dependence and frustration when the technology does not work as expected.

Dependency in vAssist: In vAssist exsiting services will be enhanced with voice interaction and supportive graphical user interfaces. This means that diverse possibilities will be offered to interact with the technical solution if one of the interaction channels (speech, GUI) does not work as expected. In addition, detailed functional testing of the solution will be done prior to any confrontation of the technology with end users to avoid frustration caused by technical errors.

7. **Exclusion:** Exclusion may be voluntary, for instance, when a user switches off, but usually it is outside people's own will. Equal rights and opportunities for all need to be built into the design of technologies since they are not achieved automatically. Exclusion can also be the result of lack of interoperability, denial of services, inadequate profiling, data mismatches or lack of data.

   Exclusion in vAssist: Since the core of vAssist is on developing a solution that is independent from the device in use (e.g. TV, PC, mobile device) the project itself covers the aspect of interoperability and denial of services when using different devices.

8. **Victimization:** Citizens have a democratic right not to be treated as criminals (unless they are criminals). Victimization as an AmI impact describes a disproportionate reaction based on unfounded suspicious and emphasizes the difficulty in being able to act anonymously.

   Victimization in vAssit: In vAssist victimization will not play a role of concern since no services will be provided that enable the user to start criminal actions.

9. **Surveillance:** Every citizen/consumer leaves electronic traces as the price of participation in the AmI society. These traces will make it possible to construct very sophisticated personal profiles and activity patterns. Although the justification for installing surveillance systems has a strong public interest, surveillance raises ethical, privacy and data protection issues. There is a clear need to delineate and define the boundaries between the private and public spheres.

   Surveillance in vAssist: In vAssist a surveillance/alarm system will be integrated. This function will only be available for private use and the connection with relevant others in cases of emergency. No public spheres will be integrated so boundaries will not have to be defined.

10. **Identity Theft:** Without appropriate security, the AmI environment may provide malicious persons many opportunities to steal identity information and to use it for criminal purposes. A new kind of crime is data laundering.

    Identity Theft in vAssist: In vAssist most advanced data protection strategies (encryption algorithms, passwords, firewalls, spam filters, etc.) will be applied to avoid unwanted access of (criminal) persons to personal data.

11. **Malicious Attacks:** Every new technology is plagued by known and/or unknown weaknesses, which threaten to serve as the backdoor for the risk of malicious attackers.

    Malicious Attacks in vAssist: In vAssist, next to the data protection strategies mentioned above, the services will be installed on a locked and controlled system to guarantee that no external access to personal user data will be possible for malicious attacks.

12. **Digital Divide:** AmI technology has the potential (because of its foreseen user friendliness and intuitive aspects) to bridge some aspects of the current digital divide, but this same technology could also widen other aspects with regard to the risk of unequal access and use.

    Digital divide in vAssist: Facing the problem of digital divide between younger and older generations is another core aspect of the vAssist systems. The project itself strives for a reduction of the digital divide by making existing services and technologies available for senior citizens. Existing services that are current only accessible by advanced users will be enhanced with voice and supportive graphical user interfaces to make them accessible not only for senior persons but also for all users with restricted fine motor skills and chronic diseases.

13. **Spamming:** Spamming encompasses several risks such as profiling, disclosure of personal data and malicious attacks.

    Spamming in vAssist: Most advanced spam filters data encryption and password strategies will be applied to guarantee that spamming and danger of malicious attacks will be reduced to a minimum.

Table 1below gives a short overview of where in this deliverable and the vAssist project in general the above mentioned 13 risks of AmIs are addressed.

Nr.	Risk	Addressed in vAssist	Section
1	Privacy	General Ethical Regulations for Research	4
		National Legislations	5
		Data Protection Plan	6
2	Security	General Ethical Regulations for Research	4

		National Legislations	5
		Data Protection Plan	6
3	Identity	General Ethical Regulations for Research	4
4	Trust	Handling of Ethical Issues in vAssist	2
		General Ethical Regulations for Research	4
5	Loss of Control	General Ethical Regulations for Research	4
6	Dependency	General Ethical Regulations for Research	4
7	Exclusion	General Ethical Regulations for Research	4
8	Victimization	Does not play a role of concern in vAssist	Does not play a role of concern in vAssist
9	Surveillance	General Ethical Regulations for Research	4
		National Legislations	5
		Data Protection Plan	6
10	Identity Theft	General Ethical Regulations for Research	4
		National Legislations	5
		Data Protection Plan	6
11	Malicious Attacks	General Ethical Regulations for Research	4

		National Legislations	5
		Data Protection Plan	6
12	Digital Divide	General Ethical Regulations for Research	4
		National Legislations	5
13	Spamming	General Ethical Regulations for Research	4
		Data Protection Plan	6

Table 1: Matching ethical risks of AmI and how they will be addressed in vAssist

However, it must be noted that one important concern addressing these potential risks of AmI is the search for a balance in the relationship between the demand for a better quality of life of older persons and their carers, the respective researches, and the rights of study participants. The issue lies in the demand for research to be designed, reviewed and undertaken in a way that ensures its integrity and quality confronted by the limitations imposed by research ethic key principles regarding the dignity of human life.

2.2 Ethical Documents

The different documents that include basic information about the vAssist project, human rights of the participants, the study procedures and applied methods are explained in this chapter and are attached in the annex section (Informed Consent form and Information letter).

2.2.1 Informed Consent (IC)

Informed consent is the process by which a participant is fully informed about the research study in which he/she is going to participate. It originates from the legal and ethical right that the participant has to be informed what happens to his/her personal data and from the ethical duty of the researcher to involve the participant in the research. This means that the individual subject has the right to be informed about the research process and outcomes.

In order to involve a human individual as a participant in research studies, the researcher will obtain the legally effective informed consent of the participant or the participant's legally authorized representative. In vAssist members of the primary (older persons) and secondary (family members / health professionals) target group will have the cognitive capabilities preserved, so that they can sign the consent by themselves. The information given to the participant or the representative will be in an understandable language to the participant or the representative person. No informed consent, wheth-

er oral or written, may include any exculpatory language through which the participant or the representative is made to waive or appear to waive any of the participant's legal rights, or releases or appears to release the researcher, the sponsor, the institution or its agents from liability for negligence.

In addition, appropriate and adequate information (e.g. the nature, duration, and purpose of the study; the method and means by which it will be conducted; any inconveniences and hazards reasonably to be expected; the effects upon his/her health, and that he/she may terminate any study at any point without specifying any reasons) will be integrated in the informed consent form in order to ensure informed consent. A model informed consent form in English for the vAssist project can be found in the annex at the end of this deliverable.

The informed consent document is the base for any informed consent that will be used for any study within the vAssist project. For each study the informed consent document will be adapted to the procedures, used methods and purpose of the study. All evaluation partners will use a translated version in order to ensure informed consent and integrity of the participants in different partner countries. All participants have the right to receive a copy of the Informed Consent form.

2.2.2 Information Letter

The aim of the information letter document is to provide basic information about the study and project in order to guarantee that participants have basic information to make decision about whether to participate or not in any study of the vAssist project. The document summarizes the main information about the project and will be used for recruitment activities. This document includes a summary of the vAssist project, the objectives, target group specifics, and a simple illustration of the vAssist system in form of scenarios. The information letter in English can be found in the Annex section in the end of this deliverable. All evaluation partners will use a translated version in order to provide basic information for potential study participants in different partner countries. Both the informed consent and the information letter are developed in a basic version for the vAssist project. Both documents will be adapted to the specific aims of following future studies within. Updates on the informed consent and information letter refer to the “Procedure” section that may vary between different studies (e.g. Wp2 Requirements Specification, WP4 Lab and Field Trial Evaluation). All participants have the right to receive a copy of the information letter.

3 vAssist Ethical Advisor

The ethical responsible person for vAssist will be:

- **Name:** Bernhard Wöckl
- **Department:** CURE – Center for Usability Research & Engineering
- **Address:** Modecenterstraße 17 / Objekt 2
- **City:** 1110 Vienna
- **Country:** Austria
- **E-Mail:** woeckl@cure.at
- **Telephone Number:** +43/1/743 54 51 -217

The main goals of the ethical advisor are to advise the vAssist consortium on ethical and privacy issues that may arise during the project and to approve all research activities before involving human individuals in any project phase.

The ethical advisor is a project member of CURE and will control all user involvement activities within the project. All tasks of this person are related with T1.4 Ethical Watch.

The ethical advisor will work close together with the primary contacts of the involved end user organizations (EURAG [AUT]: Eva Reithner, eurag@eurag.at; APHP [France]: Grégory Legouverneur, gregory.le-gouverneur@brc.aphp.fr). This will guarantee that ethical issues are controlled and reviewed from different independent organizations from different partner countries.

3.1 Tasks Assigned

The main task of the ethical advisor is to give advice and feedback about the actions that must be followed in the project in order to maintain:

- A holistic privacy framework
- Confidentiality and security
- The ethical considerations about the characteristics of the human being as an individual and as a social being, addressing:
    - Safety, well-being, voluntariness and rights of the participant(s).
    - Scientific validity of research actions.
    - Fair selection of the subjects for user studies in the project. This is a justice principle.
    - Favorable proportion of risk vs. no risk in user studies when interaction with the vAssist system takes place. This is related to the non-maleficence principle.
    - Considerations about the user's authenticity right
    - Independent evaluation with each user
    - Informed consent and information letter
    - Respect to the participants

This deliverable is expected by month 2 previous to the start with the first user involvement for gathering user requirements in WP2. As experts in ethical issues, the ethical advisor of the project partner CURE together with the end user organizations APHP (FRA) and EURAG (AUT) will review and confirm this deliverable and all other documents that refer to active user involvement and data privacy issues in the vAssist project.

Before starting any user involvement a meeting (skype, telco, physical) between CURE, APHP and EURAG will be scheduled. The objective is to explain and define how the partners plan to carry out studies with end users. In these meetings ethical issues about how vAssist must work for the following study will be discussed. This is a critical aspect for all implications for the vAssist development and design process. This means that possible privacy and security problems will be solved when uncovered and taken into account during the design of the vAssist system. Moreover, at the end of the project a specific meeting together with CURE (AUT), APHP (FRA) and EURAG (AUT) will be organized to deal with all ethical issues that were uncovered during the whole project duration.

3.2 Work Planning

For future activities that will involve end users in the vAssist project, technical developments and dissemination actions, the following information exchange is planned between the ethical advisor (CURE: Bernhard Wöckl) and the primary contacts from the involved end-user organizations (EURAG: Eva Reithner; APHP: Grégory Legouverneur):

- **Information exchange before and after activities in WP2 (Requirements Specification):**
  - Focus on how user studies have to be carried out, whether any ethical problem has arisen and how the problem was solved.
  - Aiming on the identification of possible failures in the performance process to be able to correct and to avoid them in following user studies.
- **Information exchange before and after the activities in WP4 (Lab and Field Trial Evaluation):**
  - Explaining and defining the way in which ethical issues will be addressed.
- **Information exchange meeting before the end of the project:**
  - A meeting (telco, skype, physical) will be organized to specify ethical recommendations about how the vAssist system should work after the project end how uncovered ethical issues can be solved.

4 General Ethical Regulations for Research

The next section summarizes selected important general ethical considerations for research involving human individuals that have to be followed in the vAssist project covering a broad range of diverse aspects that have to be regarded and considered when developing IT based systems with active user involvement from different perspectives (general social science research, research in the field of IT and healthcare, research in the field of electronic assistive technologies, medical research involving human subjects). The described key principles in the sections below specify the treatment of human individuals and guide related research and development activities. The selection of the ethical key principles has been taken place based on possible ethical considerations that may arise during the project duration covering a broad variety of different perspectives and risks of AmIs that are important for the scope of the vAssist project:

- A) Ethics for social science research involving human beings
- B) Ethics for information science and technology in the field of healthcare
- C) Ethical recommendations for Electronic Assistive Technologies (EAT)
- D) Ethics related to (medical) research involving human subjects

These ethical key principles are seen as the basic guidelines for all activities with active user involvement, technical developments and disseminations within the vAssist project.

The Framework for Research Ethics (FRE) [1] provides ethical key principles for social science research activities. The IMIA Code of Ethics for Health Information Professionals [8] provides ethical key principles for information science and technology in the fields of healthcare, medical, health and bioinformatics. The report on Electronic Assistive Technology (EAT) [7] provides ethical recommendations for Electronic Assistive Technologies (EAT) and the Declaration of Helsinki [6] from the World Medical Association (WMA) provides ethical key principles for physicians and other persons in (medical) research involving human subjects.

4.1 Framework for Research Ethics (FRE)

According to the Framework for Research Ethics (FRE) [1] social research must comply with the demand that:

"Social scientists have to ensure that research participants are aware of and consent to arrangements are made with regard to the management and security of data, the preservation of anonymity, and any risk that might arise during or beyond the project itself, and how these might be minimized or avoided."

This, however, imposes certain limitations upon the design of the research process and study conduction, which should be under the scrutiny of an autonomous body.

"While ethical principles and review concern the rights, dignity and safety of research subjects, research governance concerns the development of shared standards and mechanisms that permit the proper management and monitoring of research and, if necessary, allow sanctions to be brought in

cases of research misconduct". These two dimensions are linked. It is clear that a strong ethical culture and literacy are dependent not only on professional self-regulation but also on sound structures of formal governance within research organizations."

According to the FRE[1] the following listed 6 principles are the ethical key principles for social research activities that have to be followed in the vAssist project:

1. **Information:** Research staff and subjects must be fully informed about the purpose, methods and intended possible use of the research, what their participation in the research entails and what risks, if any, are involved.
2. **Privacy:** The confidentiality of information supplied by research subjects and the anonymity of respondents must be respected.
3. **Voluntariness:** Research participants must participate in a voluntary way, free from any coercion.
4. **Prevention:** Harm to research participants must be avoided.
5. **Independency:** The independence of research must be clear, and any conflicts of interest or partiality conflicts must be explicit.
6. **Standards:** Following these principal ethical guidelines the researchers ensure that their investigation will develop with high ethical standard.

4.2 IMIA Code of Ethics for Health Information Professionals

The International Medical Informatics Association (IMIA) is an independent organization established under Swiss law in 1989. IMIA plays a major global role in the application of information science and technology in the fields of healthcare and research in medical, health and bio-informatics. The basic goals and objectives of the association are:

- To promote informatics in health care and research in health, bio- and medical informatics
- To stimulate research, development and routine application
- To move informatics from theory into practice in a full range of health delivery settings, from physician's office to acute and long term care
- To foster the dissemination of results and exchange of knowledge, information and technology
- To promote education and responsible behavior
- To represent the medical and health informatics field within the World Health Organization (WHO) and other international professional and governmental organizations.

Next to the ethical principles from the Framework for Research Ethics (FRE) [1] the IMIA Code presents a list of 6 additional fundamental ethical principles that will be applied in vAssist [8]:

1. **Principle of Autonomy:** All persons have a fundamental right to self-determination. For any participation in the vAssist project users have the right for informed consent and control their

personal data. Both must be respected at all times (this includes ethical issues of confidentiality and data security).

2. **Principle of Equality and Justice:** All persons are equal as persons and have a right to be treated accordingly. Any study and general operation of any device should take into account the legitimate interests of third parties, and not incorporate or promote any bias based on gender, culture, nationality, or other sources of social prejudice (this includes a fair selection of the subjects for any user study). Benefits of any study will be shared with the involved communities (this includes publication and dissemination of the results of any study).

3. **Principle of Beneficence:** All persons have a duty to advance the good of others where the nature of this good is in keeping with the fundamental and ethically defensible values of the affected party. Any study and general operation of any device should benefit the participant according to his or her own conception of the good (this is a non-paternalistic interpretation of the principle, and includes making sure that participants hold authentically those conceptions).

4. **Principle of Non-Maleficence:** All persons have a duty to prevent harm to other persons insofar as it lies within their power to do so without undue harm to them. Any study and general operation of any device should not harm the participant, or put him or her under unacceptable risk (this also includes risks related to data privacy).

5. **Principle of Impossibility:** All rights and duties hold subject to the condition that it is possible to meet them under the circumstances that obtain.

6. **Principle of Integrity:** Whoever has an obligation has a duty to fulfill that obligation to the best of her or his ability.

Further, under the title *General Principles of Informatics Ethics* follows an elaboration of the above stated 6 fundamental ethical principles to 7 ethical principles that have to be followed in health informatics research [8] dealing as guidelines for vAssist:

1. **Principle of Information-Privacy and Disposition:** All persons have a fundamental right to privacy, and hence to control over the collection, storage, access, use, communication, manipulation and disposition of personal and private data.

2. **Principle of Openness:** The collection, storage, access, use, communication, manipulation and disposition of personal data must be disclosed in an appropriate and timely fashion to the subject of those data.

3. **Principle of Security:** Data that have been legitimately collected about a person should be protected by all reasonable and appropriate measures against loss, degradation, unauthorized destruction, access, use, manipulation, modification or communication.

4. **Principle of Access:** The subject of an electronic record has the right of access to that record and the right to correct the record with respect to its accurateness, completeness and relevance.

5. **Principle of Legitimate Infringement:** The fundamental right of control over the collection, storage, access, use, manipulation, communication and disposition of personal data is conditioned only by the legitimate, appropriate and relevant data needs of a free, responsible and democratic society, and by the equal and competing rights of other persons.

6. **Principle of the Least Intrusive Alternative:** Any infringement of the privacy rights of the individual person, and of the individual's right to control over personal sensitive data as mandated under Principle 1, may only occur in the least intrusive fashion and with a minimum of interference with the rights of the affected person.

7. **Principle of Accountability:** Any infringement of the privacy rights of the individual person, and of the right to control over personal sensitive data, must be justified to the affected person in good time and in an appropriate fashion.

4.3 Report on Electronic Assistive Technology (EAT)

The increasing availability of modern information and communication technology (ICT) in the home, school and workplace has enhanced popular awareness of its potential for countering impairment or age related restrictions, be it congenital or following on from illness, injury or due to age. People with disabilities or age related restrictions can be enabled to realize a greater potential, to develop greater independence and to become less dependent on others.

The rapidity of technological progress has outpaced the ability to safely deliver an effective, integrated provision. Following the report of the National Health Service (NHS) and Social Services in England and Wales 4 ethical key recommendations are arising for the development of EATs that also have to be regarded in the vAssist project [7].

1. **Availability:** Electronic Assistive Technology (EAT) should be available equitably, appropriately and in a manner which is both efficient and cost-effective.

2. **Holistic Assessment**: Comprehensive holistic assessment necessitates that potential user problems are properly identified and delineated. Whilst this may often be possible at a local level, complex problems demand that dedicated medical, scientific and technological as well as therapy expertise should be available at a network of specialists.

3. **Service Delivery**: Service delivery should be timely and appropriate. It should be overseen from each hub by specialist personnel who should adopt responsibility for equipment procurement, provision and maintenance. Working closely with locally based professionals they should promote the effective, efficient and safe usage of EAT.

4. **Standards**: There is a need to define and establish international standards for the provision of EATs to develop evidence based practice and oversee service delivery.

4.4 Declaration of Helsinki

The World Medical Association (WMA) has developed the *Declaration of Helsinki* as a statement of ethical principles to provide guidance to physicians and other persons in (medical) research involving human subjects [6]. In general, medical research involving human subjects includes research on identifiable human material or identifiable data. The focus of the vAssist project will not be on medical research per se but several key principles of this declaration relate to general ethical research principles that have to be followed by the vAssist project consortium. Below the general ethical key principles from the Declaration of Helsinki are listed and adapted for the application in vAssist.

The following 16 ethical key principles are an excerpt from the Declaration of Helsinki, adapted to be applied in the vAssist project:

1. **Well-Being**: The well-being of the individual research subject must take precedence over all other interests.

2. **Standards:** Research involving human individuals must follow ethical standards that promote respect for all human subjects and protect their health and rights**.**

3. **Legislation and Regulation:** National and international ethical, legal and regulatory norms and standards for research involving human subjects must be followed. No national or international ethical, legal or regulatory requirement should reduce or eliminate any of the protections for research subjects.

4. **Protection:** It is the duty of the (medical) researcher who participates in (medical) research to protect the life, health, dignity, integrity, right to self-determination, privacy, and confidentiality of personal information of research subjects.

5. **Scientific Principles:**(Medical) research involving human subjects must conform to generally accepted scientific principles, be based on a thorough knowledge of the scientific literature, other relevant sources of information, and adequate laboratory.

6. **Prevention:** Appropriate caution must be exercised in the conduct of (medical) research that may harm the environment.

7. **Written Protocol:** The design and performance of each research study involving human subjects must be clearly described in a research protocol. The protocol should contain a statement of the ethical considerations involved and should indicate how the principles of the Helsinki Declaration have been addressed. The protocol should include information regarding funding, sponsors, institutional affiliations, potential conflicts of interest, incentives for subjects and provisions for treating and/or compensating subjects who are harmed as a consequence of participation in the research study. The protocol should describe arrangements for

post-study access by study subjects to interventions identified as beneficial in the study or access to other appropriate care or benefits.

8. **Approval:** The research protocol must be submitted for consideration, comment, guidance and approval to a research ethics committee before the study begins. This committee must be independent of the researcher, the sponsor and any other undue influence. It must take into consideration the laws and regulations of the country or countries in which the research is to be performed as well as applicable international norms and standards but these must not be allowed to reduce or eliminate any of the protections for research subjects. The committee must have the right to monitor ongoing studies. The researcher must provide monitoring information to the committee, especially information about any serious adverse events. No change to the protocol may be made without consideration and approval by the committee.

9. **Qualification of Research Staff:** (Medical) research involving human subjects must be conducted only by individuals with the appropriate scientific training and qualifications. Research on patients or healthy volunteers requires the supervision of a competent and appropriately qualified physician or other health care professional. The responsibility for the protection of research subjects must always rest with the physician or other health care professional and never the research subjects, even though they have given consent.

10. **Study Participants:** (Medical) research involving a disadvantaged or vulnerable population or community is only justified if the research is responsive to the health needs and priorities of this population or community and if there is a reasonable likelihood that this population or community stands to benefit from the results of the research.

11. **Risk Evaluation:** Every (medical) research study involving human subjects must be preceded by careful assessment of predictable risks and burdens to the individuals and communities involved in the research in comparison with foreseeable benefits to them and to other individuals or communities affected by the condition under investigation.

12. **Voluntariness:** Participation by competent individuals as subjects in medical research must be voluntary. Although it may be appropriate to consult family members or community leaders, no competent individual may be enrolled in a research study unless he or she freely agrees.

13. **Protection of Privacy:** Every precaution must be taken to protect the privacy of research subjects and the confidentiality of their personal information and to minimize the impact of the study on their physical, mental and social integrity.

14. **Information:** In (medical) research involving competent human subjects, each potential subject must be adequately informed of the aims, methods, sources of funding, any possible conflicts of interest, institutional affiliations of the researcher, the anticipated benefits and potential risks of the study and the discomfort it may entail, and any other relevant aspects of the study. The potential subject must be informed of the right to refuse to participate in the study

or to withdraw consent to participate at any time without reprisal. Special attention should be given to the specific information needs of individual potential subjects as well as to the methods used to deliver the information. After ensuring that the potential subject has understood the information, the physician or another appropriately qualified individual must then seek the potential subject's freely-given informed consent, preferably in writing. If the consent cannot be expressed in writing, the non-written consent must be formally documented and witnessed.

15. **Informed Consent:** For (medical) research using identifiable human material or data, physicians must normally seek consent for the collection, analysis, storage and/or reuse.

16. **Publication and Dissemination:** Authors, editors and publishers all have ethical obligations with regard to the publication of the results of research. Authors have a duty to make publicly available the results of their research on human subjects and are accountable for the completeness and accuracy of their reports. They should adhere to accepted guidelines for ethical reporting. Negative and inconclusive as well as positive results should be published or otherwise made publicly available. Sources of funding, institutional affiliations and conflicts of interest should be declared in the publication. Reports of research not in accordance with the principles of this Declaration should not be accepted for publication.

5 National Regulations Of Each Country Involved In vAssist

The next section summarizes the national legislations from Austria and France that have to be regarded during the vAssist project. This summary specifies how each partner has to manage the ethical issues in his/her country from a legal point of view next to the general ethical principles from section 3 General Ethical Regulations for Research.

The vAssist project will carefully consider all ethical aspects at every moment and in every situation to ensure an adequate protection of the data privacy and the personal rights of the users. This procedure will not only affect the primary end users (older persons) participating in the project but also relevant other persons and organizations participating in vAssist including national legal limitations and regulations that must be applied to any project activity.

Research and development in the vAssist project will be conducted in Austria and France. In addition, lab and field trials and evaluation studies will be performed in Vienna (Austria) and Paris (France).

5.1 Austrian Legislation

In Austria, the following legislation will have to be taken into account in the vAssist project.

5.1.1 Data Privacy and Security

Datenschutzgesetz (DSG 2000), BGBl. I Nr. 165/1999 [2]: This act regulates the protection of personal data in Austria (i.e. the Austrian implementation of the European directive on data protection).

Informationssicherheitsgesetz (InfoSiG 2002), BGBl. I Nr. 23/2002 [9]: This act regulates basic rights of data privacy and the duty to give information.

Gesundheitstelematikgesetz (GTelG), BGBl. I Nr. 179/2004 [3]: This act regulates data security procedures when dealing with electronic health data.

5.1.2 Non-Discrimination

Wiener Antidiskriminierungsgesetz (LBI 35/2004) [10]: This act regulates the abatement of discrimination referring to the access to social, health and education as well as public services. It focuses on the non-discrimination and equal treatment regarding sex, age, disability, ethnic group, religion, ideology and sexual orientation [10].

5.2 French Legislation

This chapter aims to specify the French legislation and procedures regarding ethical principles in research projects involving human beings.

5.2.1 Health related Research on Human Beings

Public Health Code (Code de la Santé Publique - CSP) [11]

In accordance with the Helsinki Declaration, the Public Health Code [11] mentions recommendations regarding ethical issues as following: informed consent, minimal risk, information and understanding, voluntariness, participants' rights, nondisclosure, confidentiality and waivers.

In France, health related research projects require an evaluation by an Ethic Committee in order to ensure the respect of National and International Ethical Recommendations. However, within this field of research, different types of studies may be implemented. The French legislation distinguishes between "bio-medical research" and other health related research. The ethical procedures to follow and related Committee to consult depend on the qualification of each particular study.

The focus of the vAssist project will not be on medical research per se. According to this law, the vAssist project can be qualified as an observatory non interventional study. This means that the project will not entail any change in medical care provided to any study participants.

Huriet Bio Medical Law (20/12/88 ; 23/01/70 & May 2002; law n°2004-806 9 august 2004) [12] is included in the CSP [11] and was modified by the European Directive 2001/20/CE (2/04/01), on 11/08/2004.

This law defines bio-medical research (RBM) as "research and experimentations on human beings in order to improve biological or medical needs and demand". All studies in the scope of this law require a prior approval by the Regional Ethic Authority and Committee (CPP / AFSAPPS), which also allows researchers to publish their results in a medical review. The majority of bio-medical studies, such as Clinical Trials, enter this definition.

However, as mentioned previously, the focus of the vAssist project will not be on medical research per se. According to this law, the vAssist project can be qualified as an observatory non interventional study, i.e. that the project will not entail any change in medical care provided to the participants. This research is outside the field of Current Care studies (soins courants) and outside Medical Device studies (dispositif medical). Therefore, the vAssist project is not in the domain of the Regional Ethic Authority and Committee.

For the vAssist project a simplified process for the research approval is aspired: A competent external Committee named "Conseil d'Evaluation Ethique pour les Recherches en Santé" or CERES, for such kind of project is different from the Committee for biomedical research stricto sensu. The CERES also provides the agreement for any further publication and will be the Committee that approves all research activities of the vAssist project that will take place in France.

5.2.2 Medical and Personal Data Protection

Medical and Personal Data Protection and privacy Act - March 4th 2002 loi 94-548 du 6 janvier 1978 [13]

The informed consent, the right to information, the protection of personal and medical data, confidentiality, privacy, are specifically regulated. The research protocol will be submitted to the Consultative Committee for Personal Data Processing in Health related Research (Comité Consultatif pour le Traitement de l'Information en matière de Recherche dans le domaine de la Santé - **CCTIRS**). The answer is notified within one month. Then the Protocol with the letter of advice of this Committee is sent for approval to the National Public Authority in charge of personal Data protection (CNIL, see section 1.1.3).

5.2.3 Protection of Personal Computerised Data

Loi Informatique et Libertés 01 1978 - 2004-801 6 august 2004 (Freedom and Computer Act) [14]

The CNIL is the National Public Authority that is in charge of the protection of personal data.

All files that contain personal computerised data must get the authorisation of this public authority. The project must be notified to the Agency of Protection through official forms and must be registered in their data base. The measurements of the security of the files containing data of personal character are regulated.

The officer responsible for the data protection must be mentioned in the protocol that is submitted to the Authority and a description of the security protection of data is requested.

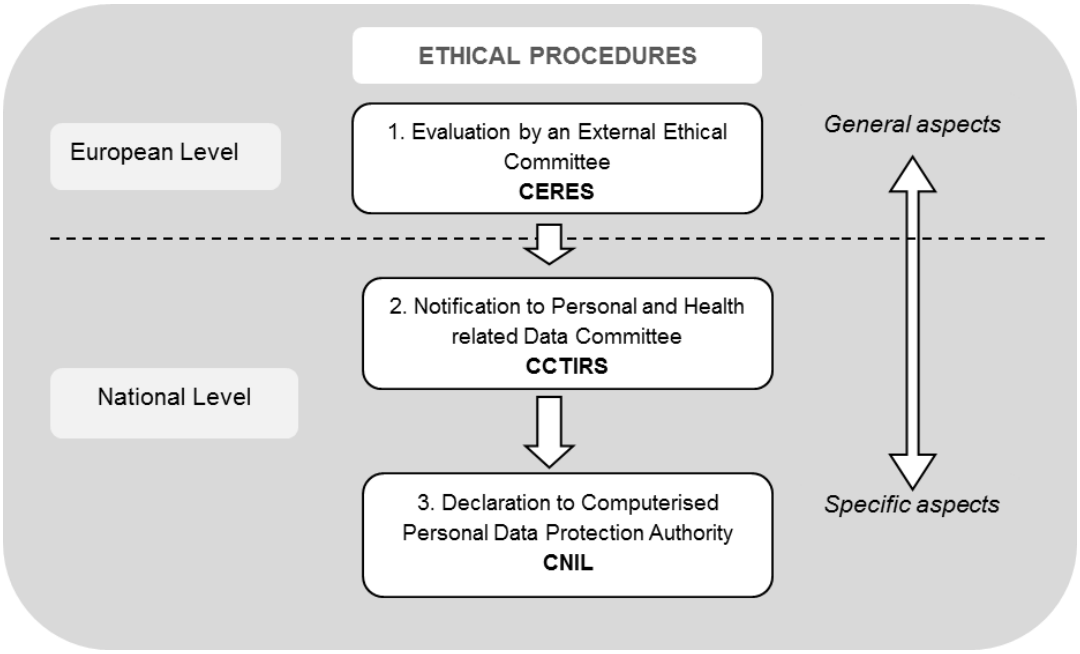

Figure 1: Ethical procedures scheme for France

The vAssist research project will be submitted by AP-HP Broca to an Ethical Committee (CERES) for example, to the Consultative Committee for Research concerning Data health. And in parallel, the protocol will be submitted to the CNIL.

6 Data Protection Plan

The following section defines the guidelines for the protection of personal and private information of study participants that will be followed in the vAssit project.

6.1 Use of Personal Data for Research

The next section specifies the guidelines for the collection, storage and erasement of private and personal data of study participants in vAssist.

6.1.1 Quality of Data

Data Collection: Personal data may be collected for processing, and undergoes such processing, only if the data is adequate, relevant and not excessive in relation to the scope and the specified, explicit and legitimate purposes for which the data is obtained.

Data Erasement: Personal data shall be erased when it has ceased to be necessary or relevant for its purpose for which it was obtained or recorded.

Research Subject Identification: Data shall not be kept in a form which permits identification of the data subject for longer than necessary for the purposes for which it was obtained or recorded.

Data Storage: Personal data shall be stored in a way which permits the right of access to be exercised, unless lawfully erased.

6.1.2 Right of Information about Personal Data Collection

Human individuals from whom personal data is requested must previously be informed explicitly, precisely and unequivocally about the following issues:

Existence of Data: The existence of a file for personal data processing, the purpose for collecting the data, and the recipients of the information.

Nature of Data: The obligatory or voluntary nature of the reply to any given question

Consequences of Data: The consequences for obtaining the data or for refusing to provide them.

Access to Data: The possibility of having the right to access, rectification, erasure and objection of personal data.

Transparency: The identity and address of the controller of the study or of his representative.

This information will be included in the vAssist Informed Consent that is attached in the annex section at the end of this deliverable.

6.1.3 Data Security

The person who controls or, where applicable, the person who processes personal data of study participants shall adopt the technical and organizational measures necessary to ensure the security of the gathered personal data and prevent their alteration, loss, unauthorized processing or access, having regard to the state of the art, the nature of the data stored and the risks to which they are exposed by virtue of human action or the physical or natural environment.

No personal data of study participants shall be recorded in files which do not meet the conditions laid down by rules regarding their integrity and security, as well as the rules governing the processing centers, premises, equipment, systems and programs.

6.1.4 Duty of Security

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

6.1.5 Right of Access

Human individuals that participate in any study shall have the right to request and obtain free of charge information on his/her personal data subjected to processing, on the origin of such data and on their communication or intended communication.

The information may be obtained by simply displaying the data for consultation or by indicating the data subjected to processing in writing, or in a copy, fax or photocopy, whether certified a true copy or not, in legible and intelligible form, and without using keys or codes which require the use of specific devices.

6.1.6 Right of Rectification or Cancellation

The person who controls shall be obliged to implement the right of rectification or cancellation of the data subject within a period of ten days.

6.2 Data Storage and Handling

Research in vAssist revolves around information about persons –their age, lifestyle, health status, behaviors and other personal data – drawn from records, scientific studies, surveys and interviews. In some cases, the information also reveals facts about relatives and relationships. These types of information are private and sensitive, although attitudes and expectations vary widely.

The protection of the privacy of participants is a responsibility of all persons involved in research with human participants. Privacy means, that the participant can control the access to personal information and is able to decide who has access to the collected data in the future.

Due to the principle of autonomy (see section 3.2 IMIA Code of Ethics for Health Information Professionals) the participants have to be asked for their agreement (see section 5.2.1 Informed Consent) before private and personal information is collected. It shall be ensured that all persons involved in research studies understand and respect the requirement for confidentiality. The participants should be informed about the confidentiality policy that is used in this research project.

Privacy plays a major role in the vAssist project and will be addressed as following:

- **Publications:** Hints to or specific personal information of any participant in (scientific) publications. It should be prevented to reveal the identity of participants in research deliberately or inadvertently, without the expressed permission of the participants.
- **Dissemination:** Dissemination of data among partners. This relates to access to data, data formats, methods of archiving (electronic and paper), including data handling, data analyses, and research communications. Restricted access to private and sensitive information within the partner organization must be guaranteed.
- **Protection:** The organization is responsible for the protection of the participant`s privacy within the organization (e.g. employers, etc.) throughout the whole vAssist project process like, communications, data exchange, presentation of findings, etc.
- **Control:** Furthermore the 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 them.
- **Information:** As already mentioned above, the protection of the confidentiality implies informing the participants about what may be done with their data (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.

6.3 Process of Encoding and Anonymization

Personal and private information of study participants shall be anonymized so that individual identities cannot be revealed. Anonymization provides a safeguard against accidental or mischievous release of confidential and private information.

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

- **Coding:** Coded information contains information, which could readily identify people. Their identity is concealed by coding and the key is held by members of the research team using this information.

- **Anonymization:** Anonymized data with links to personal information can only be accessed by the research team that holds it, but contains coded information, which could be used to identify people. The key to the code is held by the custodians of a larger research database.
- **Unlinked Anonymization:** Anonymized data contains nothing that has reasonable potential to be used 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. number, e-mail address, full postcode
- Any identifying reference number
- Photograph or names of relatives

Researcher and database developer should always consider – when designing studies, before passing information to others, and before publishing information - whether data contains combinations of such information that might lead to the identification of individuals or very small groups.

Within vAssist partners will follow the unlinked anonymization data policy, excluding users having rare diseases and any other identifiers, except age, gender and nationality. Once anonymized, the data will not allow tracing back the participant in any way.

Data will be encoded and anonymized using numerical codes. During user studies and development stages, the correspondence with the users will be saved into a local database, which will be encrypted.

6.4 Security Measures for Storage and Handling

The most secure storage, delivery and access of personal information as well as managing the rights of the users will be selected. In this way, there is complete guarantee that the accessed, delivered, stored and transmitted content will be managed by the right persons, with well-defined rights, at the right time.

State of the art firewalls, network security, encryption and authentication processes will be used to protect collected data. Firewalls prevent the connection to open network ports, and exchange of data will only be done through consortium known ports, protected via IP filtering and password. Where possible (depending on the facilities of each partner) the data will be stored in a locked server, and all identification data will be stored separately.

A metadata framework will be used to identify the data types, owners and allowable use. This will be combined with a controlled access mechanism and in the case of wireless data transmission with efficient encoding and encryption mechanisms.

All sensible data will be encrypted and protected during storage and process so that the user's identity and privacy will not be compromised as a result of the introduced technology. Context awareness

technologies will also contribute to determine which content should be registered and which should not be annotated.

6.5 Security Enforcement within the Project

Data will be collected at different research sites within surveys, interviews, experiments and evaluation studies. The collected data will be stored in a secure server, only visible to the research site network, in a locked room at each of the research locations. Anonymous and identity data will be stored separately, and only the project leader will have access to the users' identities.

Anonymity will be guaranteed by separating identifiable data from anonymous data. Each user will get a unique identifier that will link one to the other, but only anonymous data will be available to researchers. If any identifiable data is required, access to it will be permitted only after explicit user permission and after agreement of the responsible data protection authority. The data will be saved for five years after the end of the project. After this time, each vAssist partner will be responsible for destroying the recorded personal data.

Authentication will be required to access stored data on the research site. Authorized researchers will have access to the recorded anonymous data after authentication with a centralized server and on a need-to-know basis. Researchers conducting studies will have access rights to add data to the identity database, synchronized with the writing of the anonymous data. No editing or reading rights will be granted to them to prevent alteration/disclosure of private user data. Collected data in the vAssist project will only be used for the purpose of the project or study. A use of private user data outside of the project scope is not allowed.

7 Conclusions

For the first actions in WP 2 carried out with end users (e.g. focus groups, interviews, cultural probe studies), no ethical problems could be identified. In general, the vAssist project implies active user involvement and the customization of the system with real information from different persons (older users, family members, health professionals). Future ethical and privacy questions may arise in further research studies and development processes. For this, the consortium of the vAssist project has elaborated a plan in order to safeguard all ethical and legal issues. The way in which user studies will be carried out and the plan to guarantee that ethical issues have been considered will be reviewed by the ethical advisor from CURE and will be approved from the two end user organizations APHP (FRA) and EURAG (AUT).

The members with expertise in ethical issues (CURE, APHP, EURAG) have approved this deliverable and the future actions that are going to be carried out with older persons, their family members and health professionals.

Due to the fact that some changes may happen during the project duration (e.g. change of legislation in a partner country) this deliverable will be updated in order to address the latest legislation and ethical key principles of each partner country.

This deliverable will be discussed in the next consortium meeting (planned for June 2012), in which all project partners are invited.

Finally, the most important actions that have been defined above are summarized in the points below. Over and above, some recommendations are given for persons that will interact with future vAssist study participants. The aim is to support researchers in deciding if he or she is acting with study participants in an ethical way.

- **National Legislation:** Each partner has to carefully read their country laws
- **Equality:** The recruitment for studies aims at an equal number of males and females. In addition, also people from different ages will be contacted for any study.
- **Informed Consent:** Study participants will have to sign an informed consent form before starting a study. It is not possible to carry out a study without signing the informed consent. Moreover, all parts of the study must be clear to the user and must be specified in this document.
- **Language:** The informed consent and all related documents will use an equal language, without discriminating people for their gender, age, sexual orientation, cultural background or other personal characteristics.
- **Data Privacy and Security:** All gathered personal data will be encrypted and protected applying a numerical code strategy. User's personal data have to be safeguarded from other people not involved in the project.
- **Publications and Dissemination:** In publications, no personal user data of study participants will be provided.

- **Cultural and Gender Differences:** At the end of any study specific analysis will be made in order to assess if gender and cultural differences are found.
- **Data Erasement:** All personal information will be saved for five years after the end of the project. After that period, each partner must destroy any recorded private user data.

For any question related to ethical issues that will arise during any study within the vAssist project, the vAssist project partners can consult the ethical advisor from CURE (Bernhard Wöckl). CURE will get in contact with the primary contact persons from APHP (FRA) and EURAG (AUT) to discuss and clarify any ethical question or risk (Details see section 2 vAssist Ethical Advisor).

8 References

[1] Framework for Research Ethics (FRE): http://www.esrc.ac.uk/_images/Framework_for_Research_Ethics_tcm8-4586.pdf (last visit: 16.12.2011)

[2] AUT: Datenschutzgesetz 2000 (DSG 2000): http://www.ris.bka.gv.at/GeltendeFassung.wxe?Abfrage=bundesnormen&Gesetzesnummer=10001597 (last visit:16.12.2011)

[3] AUT: Gesundheitstelematikgesetz (GtelG): http://www.ris.bka.gv.at/GeltendeFassung.wxe?Abfrage=Bundesnormen&Gesetzesnummer=20003885 (last visit: 16.12.2011)

[4] Aarts, E. and Marzano, S. (2003). The new everyday: views on ambient intelligence. 010 Publishers, Rotterdam,Netherlands, 2003

[5] Wright, David, Gutwirth, S.; Friedewald, M.; Vildjiounaite, E.; Punie, Y. (Eds.), Safeguards in a World of Ambient Intelligence, Springer, Dordrecht, 2010.

[6] Declaration of Helsinki:http://www.wma.net/en/30publications/10policies/b3/17c.pdf (last visit: 19.12.2011)

[7] Report on Electronic Assistive Technology (EAT): http://www.bsrm.co.uk/Publications/EATabstract.pdf (last visit: 19.12.2011)

[8] IMIA Code of Ethics for Health Information Professionals: http://www.imia-medinfo.org/new2/pubdocs/Ethics_Eng.pdf (last visit: 19.12.2011)

[9] AUT: Informationssicherheitsgesetz: http://www.ris.bka.gv.at/GeltendeFassung.wxe?Abfrage=Bundesnormen&Gesetzesnummer=20001740 (last visit: 19.12.2011)

[10] AUT: Wiener Antidiskriminierungsgesetz: http://www.wien.gv.at/recht/landesrecht-wien/landesgesetzblatt/jahrgang/2004/html/lg2004035.htm (last visit: 19.12.2011)

[11] FRA: Code de la Santé Publique (CSP) http://www.legifrance.gouv.fr/affichCode.do?cidTexte=LEGITEXT000006072665&dateTexte=20120119 (last visit 19.01.2012)

[12] FRA: Loi n° 94-630 du 25 juillet 1994 modifiant le livre II bis du code de la santé publique relatif à la protection des personnes qui se prêtent à des recherches biomédicales. Loi dite loi Huriet. http://www.legifrance.gouv.fr/affichTexte.do?cidTexte=LEGITEXT000005616269&dateTexte=20110415 (last visit 19.01.2012)

[13] FR: Loi n° 94-548 du 1 juillet 1994 relative au traitement de données nominatives ayant pour fin la recherche dans le domaine de la santé et modifiant la loi n° 78-17 du 6 janvier 1978 relative à l'informatique, aux fichiers et aux libertés :http://www.legifrance.gouv.fr/affichTexte.do?cidTexte=JORFTEXT000000547135&dateTexte= (last visit 19.01.2012)

[14] Loi n° 2004-801 du 6 août 2004 relative à la protection des personnes physiques à l'égard des traitements de données à caractère personnel et modifiant la loi n° 78-17 du 6 janvier

1978 relative à l'informatique, aux fichiers et aux libertés (1). http://www.legifrance.gouv.fr/affichTexte.do?cidTexte=JORFTEXT000000441676&dateTexte= (last visit 19.01.2012)

9 Annexes

9.1 Informed Consent

INFORMED CONSENT

Title of the Project:	vAssist - Voice Controlled Assistive Care and Communication Services for the Home
Website:	http://vassist.cure.at
Coordinator:	Univ. Prof.Dr. Manfred Tscheligi, CURE – Center for Usability Research & Engineering, Modecenterstraße 17 / Object 2, 1110 Vienna, Austria
Leading Local Investigator:	Mag. Bernhard Wöckl
Institution:	CURE – Center for Usability Research & Engineering
Financed by:	EC, BMVIT, FFG, ANR
Programme:	AAL Joint Programme (AAL JP) http://www.aal-europe.eu/
Call:	Call 3 - ICT-based Solutions for Advancement of Older Persons' Independence and Participation in the "Self-Serve Society"
Project Number:	AAL-2010-3-106
Project Type:	Cooperative Project
Project Duration:	36 Months
Project Start - End:	1 December 2011 – 30 November 2014

The study described in this document is part of the research project *"vAssist - Voice Controlled Assistive Care and Communication Services for the Home"*. The European Union (EU) and the BMVIT on behalf of the FFG finance this project under the AAL Joint Programme (Project number: AAL-2010-3-106).

This informed consent document may include words that you may not understand. If that is the case, please ask the contact researcher or any other staff of the study to fully explain the meaning of the word or piece of information you do not understand. You may take a copy of this consent to think about it or talk to your family before making any decision. At all times, we assure the compliance of the current legislation.

I. INTRODUCTION

You have been invited to take part in a research study of the *vAssist* project. Before making a decision on whether you want to participate or not, please read this document carefully. Please ask all the questions you may have so you can be completely sure that you understand the scope and procedure of the study, including risks and benefits.

II. PURPOSE OF THE STUDY/PROJECT

The general objective of the *vAssist* project is to provide voice controlled Home Care and Communication Services for two target groups of older persons (chronic diseases; fine-motor skill restrictions). The main goal is the development of simplified and adapted interface variants for tele-medical and communication applications using multilingual natural voice interaction and supportive graphical user interfaces.

III. PARTICIPANTS IN THE STUDY AND POSSIBLE PARTICIPATION

We kindly request your voluntary participation in this research study. This informed consent includes information on the following research study. We would like to assure that you are perfectly informed about the purpose of the study and what your participation in it implies.

Please ask to clarify any section in this informed consent document you do not understand. Please, do not sign if you are not sure that you have understood all the aspects of the study and its objectives.

The participation in this study is totally voluntary. You can give up at any moment without being penalized.

The criteria for participating in this study are as following:

- Being an older person (> 65 years) suffering from a chronic disease or fine-motor skill restrictions
- Being a family member or caregiver of an older person (> 65 years) suffering from a chronic disease or fine-motor skill restrictions
- Being a health professional caring for an older person (> 65 years) suffering from a chronic disease or fine-motor skill restrictions

Only in Austria: At the end of the study you will receive a financial compensation depending on your time spent and your valuable input in the amount of 20 to 80 EUR.

IV. PROCEEDINGS:

Within the *vAssist* project users of the above defined target groups will be invited to requirements, lab and field trial studies of the developed system prototypes. Within these studies users will have the chance to give information on requirements, needs and wishes in early project phases. In further project phases users have the chance to try the prototypes (lab trials, field trials) and give feedback concerning usability and user experience that will be used to refine and optimize the system. Participants will have to perform specific tasks related to the prototype as well as to answer questionnaires and interviews regarding user experience and usability aspects of the system. Lab studies will be audio and video recorded for backup and analysis reasons. Field trials will include diverse log-file recordings.

Place of the Study:

- Austria: CURE Experience Labs
- France: Premises of APHP

Duration of the Study:

- Focus Groups / Requirements Phase: ~ 2 hours
- Lab Trials / Usability Evaluation: ~ 1,5 hours

V. RISKS OR INCONVENIENT

No risks are foreseen. You are only requested to be available to participate in the study.

VI. BENEFITS

The personal benefit from participating in any study of the *vAssist* project is that you can make a substantial contribution to the development of future technologies focusing on the enhancement of the quality of life of older persons and supporting an independent life-style. In any case, the data collected in this study will lead to a deeper and better knowledge and understanding of the wishes and needs of older persons and their carers as well as their social environment to enhance future voice controlled tele-medical and communication services.

VII. PRIVACY AND CONFIDENCIALITY

Your registered and/or recorded responses will not include any personal identification information. Hence, it will not be possible to identify you after your participation in any study. Recorded information will be processed during the phase of data analysis and will be included in project internal reports or later in scientific publications. It will not be possible to identify the source of the information, observing at all times:

Austria: The „Bundesgesetz über den Schutz personenbezogener Daten (Datenschutzgesetz 2000 - DSG 2000)"

> "According to the law aforementioned, we inform you that all provided personal data that will be scientifically analysed will be coded from CURE so that it will not be possible to identify your name or other personal information about you in the results of the scientific analysis. All provided personal data will be stored in a file store that can only be accessed by partners that are active involved in the *vAssist* project. None of the provided personal data will be handled out to third parties."

The results of this study may be published in scientific magazines, conference proceedings or books. Complete anonymity of personal data is guaranteed by the *vAssist* partners.

The authorization for the use and access to this information with study purposes is completely voluntary. This authorization is valid until the end of the study unless you decide to cancel it before. If you should decide to deny your consent, please contact the leading investigator and let her/him know of your intention of leaving the study.

You can contact the leading investigator at the following address:

Mag. Bernhard Wöckl

CURE

Modecenterstraße 17

Objekt 2

1110 Vienna

Austria

+4317435451-217

woeckl@cure.at

From the moment you withdraw from the *vAssist* project, your data will not be used in any further phase of the project. However, documents that have already been published or are parts of the study that have been finished will not be able to be altered.

Your decision to whether or not give your authorization for the use and diffusion of the information provided by you is completely voluntary. However, if you do not provide us with your authorization now or if you cancel it in the future, you will not be able to participate in this study.

VIII. CONTACT PERSONS

For further information about your rights as a participant in the investigation, or if you are not satisfied with the way this study is being carried out, or if you have any question or complaint during the investigation, please contact the leading investigator:

Mag. Bernhard Wöckl

CURE

Modecenterstraße 17

Objekt 2

1110 Vienna

Austria

+4317435451-217

woeckl@cure.at

IX. CONFIRMATION

Your participation in this study is only possible if you freely and independently sign this informed consent document to authorize us to use the data you provide. If you do not wish to do so, please do not subscribe and do not participate in this study.

I have read the information in this informed consent document or the information has been read to me in an adequate way. All of my questions about the study and my participation in it have been answered.

Mark one of the following with an X:

__I read all the information in this form.

__The information in this informed consent was read to me by:……..

All the questions that I had have been answered by:……

I authorize the use and analysis of my answers to the entity aforementioned for the purposes above indicated. Signing this informed consent does not imply giving up to any legal rights. I accept in a voluntary way to participate in this investigation carried out by CURE and the rest of the partners of the *vAssist* Project. I understand that I have the right of having a copy of this informed consent. Therefore, a copy will be provided to me.

Name and surname of the participant:

……

Date:

……

Signature of the participant

……

Name and surname of the researcher

……

Date:

……

Signature of the researcher:

……

X. PHOTO, VIDEO AND AUDIO RECORDING

The study is led by:

Mag. Bernhard Wöckl

CURE

Modecenterstraße 17

Objekt 2

1110 Vienna

Austria

+4317435451-217

woeckl@cure.at

As part of this research project, photograph, videotape and audiotape recordings during the participation in the study will be done.

I have received a thorough description of the purpose and procedures for any recordings and I give my consent to allow CURE use the recordings or parts of the recordings for analysis, related studies and project results, as well as for marketing and PR purposes of *vAssist*. I understand that all information will be kept confidential and will be reported in an anonymous way.

Name and surname of the participant:

.....

Date:

.....

Signature of the participant

.....

Name and surname of the researcher

.....

Date:

.....

Signature of the researcher

.....

Figure 2: vAssist Informed Consent (IC) Form

9.2 Information Letter

Information Letter for the vAssist Project

1 Aim of vAssist

The general aim of the vAssist project is to provide voice controlled **Home Care and Communication Services** for two target groups of older persons (persons suffering from chronic diseases and persons with (fine) motor skill restrictions). The main goal is the **development of simplified and adapted interface** variants for existing telemedical and communication applications using **multilingual natural voice interaction** and supportive **graphical user interfaces**.

vAssist aims to enhance the perceived quality of Home Care and Communication Services by achieving channel independence in the delivery of vAssist services, so that existing hardware and interfaces in the home of the users can be used such as PC, TV, mobile phones or tablets.

In specific, it is pretended to develop a supportive solution for two service areas:

1. **Communication**
   - Speech to message (SMS, E-Mail) and vice versa (= speech to text facilities): Users can access message communication services that would normally require "touch or press"-input.
   - Handling of communication device (PC, TV, mobile phone, tablet): Persons can initialize phone or video calls, browse the address book, internet, etc.
2. **Well-Being / Health Care**
   - Emergency calls from everywhere in the house and outside: Users can set up social alarms, and make emergency calls (and every day calls) from everywhere in the house and outside.
   - Routine data management services: For older persons suffering from chronic diseases. Daily routine questionnaires and personal diary functionalities can be executed via voice interaction.
   - Cognitive games: Brain training games are operated via voice and supportive graphical user interfaces (GUI).
   - Reminder Functions: Medical, social and other reminders can be accessed via voice interaction.

2 Who are the Target Users

The vAssist project focuses on *older persons (> 65 years)* from *both genders*. These persons may show *restrictions in their vision, eyesight and/or hearing*. In addition, they have at least *little experience* with the use of *modern ICT* (Information and Telecommunication).

Diverse combinations of the following additional characteristics are in the focus of the project:

- **Older persons** that show *restrictions* in their *(fine) motor skills* that lead to problems in the use of mouse and keyboard or touch and/or mobile devices. They may also suffer from different *limitations at the upper limb* that hinder them in using technical devices
- **Older persons** that suffer from a *chronic disease* (e.g. diabetes, rheumatism, arthritis, high blood pressure, cardiovascular diseases, etc.). These persons also may receive stationary medical care or supportive home care services. Persons may show *age related problems* with their *memory skills* (not diagnosed as a disease such as MCI [Mild Cognitive Impairment], Alzheimer's Disease, Dementia).

3 Examples of what vAssist will be able to do

Below, some examples of what vAssist will be able to do are shown.

vAssist will implement a *voice interface* (and a *supportive graphical user interface*) for existing communication and tele-medical services to support the interaction of older persons with (fine) motor skill restrictions that have problems in using technical devices. The devices where the services can be used will be the TV set, PC, mobile phone or a tablet PC. The scenarios below give a first outline about the idea of the vAssist system.

Scenario 1

John is suffering from problems with his fine motor skills. However he is keen on writing SMS and E-mail messages to his daughter. On bad days (sometimes it is better, some days his disease is worse) he is not able to use the touch screen nor the keyboard of his PC or mobile phone.

Using vAssist John is able to go beyond voice calls and can "write" E-mails and SMS using text-to-audio-visual speech functionalities (see Figure 1).

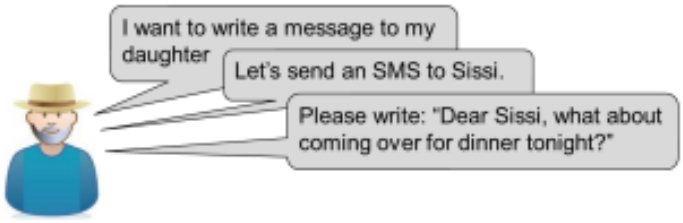

Figure 1: Writing a message using vAssist voice interaction

Scenario 2

Sissi is living with a tele-medical application of the vAssist system.

Using this application she is able to initialize voice or phone calls (to friends/relatives AND/OR health personnel) using speech, including the use of phone and address book.

As she is living alone vAssist gives her a secure feeling as she is able to initialize emergency calls everywhere from the house using vAssist voice and speech interaction (e.g. after a [non-clinical] fall) (see Figure 2).

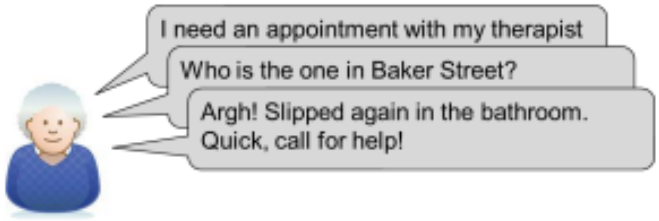

Figure 2: Initiating an emergency call using vAssist voice interaction

Scenario 3

Frank suffers from a chronic disease. His therapy requires him to enter daily a 13 item, multiple choice questionnaire, info on his drug and food intake and his physical activities. For Frank it is a hard and time-consuming task since he has problems with his fine motor skills that hinders him in using the keyboard of his PC.

vAssist provides him a facilitation of data input via natural language (voice/virtual agent) controlled interfaces and a translation into machine-readable data (see Figure 3).

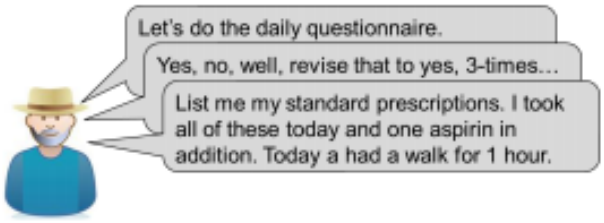

Figure 3: Filling in daily routine medical questionnaire using vAssist voice interaction

Figure 3: vAssist Information Letter