**HERMES – Cognitive Care and Guidance for Active Aging**
FP7-ICT 216709
Specific Targeted Research or Innovation Project

Start date of project: January 1, 2008
Duration: 36 months

# D.8.3 Ethical Guide and Manual including relevant legislation guidelines

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HERMES
Cognitive Care and Guidance for Active Aging - Ref. FP7 216709

Version: 1.0
Date: 30/06/2009
Dissemination level: (PU, PP, RE, CO): PU

Project Co-Funded by the European Commission within the 7th Framework Programme

**Abstract**

As the ethical issues in the HERMES project have already been identified, now it is necessary to develop strategies to address them in both the user trials and when users interact with HERMES system in live operations. The goal of this deliverable is to describe these strategies and, also to get feedback from the ethical advisors before starting actions in which end users are implied. After the approval of this document each one of the members of the consortium will be able to identify potential privacy and security risks and, more important, to know what they must do in order to avoid or minimize them.

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# 1. Introduction

## *1.1 Background*

HERMES system will support ageing people, who are suffering from normal, age-related, cognitive decline through the capture of content of certain personal information in audio and images. Sometimes, only the HERMES' user will appear in the recordings while, in certain situations, also other people will be present. In these situations, privacy is a concern since image and audio recordings are very personal and sensitive information. Besides, the privacy of both the user and the conversational partner needs to be safeguarded. Everyone has the right to be informed about the fact that he or she may be recorded. For this reason, HERMES must be transparent with the others and it has to accomplish the European Legislation, keeping privacy of the users and the other persons who interact with them.

As it is usual in the projects that follow a user-centred design, the system is tested with real users who are included in the design process. This implication implies to test the system, or the concept of it, several times before the end of the project. In the HERMES project two user trials are planned: the first one in a lab environment while the second one will be carried out in real situations. The way in which all the data privacy and security issues may arise in these tests must be specified before they take place. Also, the principles of respect for autonomy, beneficence, non-maleficence and justice will be followed.

This deliverable addresses the way in which ethical issues are going to be considered in both: in the HERMES project, the two trials that will be done, and the measures that will be taken into account in HERMES live operations. An external ethical advisory board independent from the consortium is going to oversee and approve this deliverable.

## *1.2 Scope of this Deliverable*

The core of the D8.3 is to create an Ethical Guide Manual. In this Manual all the factors and considerations that should be taken into account before starting the research activities with humans are addressed. The aim is to describe how the consortium is going to maintain security, privacy and confidentiality norms and respects the common values of respect for autonomy, beneficence, non-maleficence and justice throughout the project. As stated before, two external ethics advisors and the Matia /Ingema /Hurkoa Ethical Committee will give their feedback and approval of this Ethical Manual.

The main impact of this deliverable will be in the area of the users' involvement and actions. But also some considerations will have an impact on the HERMES technological design, as described in this deliverable. In order to address the privacy issues some technological actions must be done (e.g. to set up a password, etc). For this reason, this deliverable is related to the actions in WP3 regarding to the development of the architecture for the data storage in combination with the work in WP4.

The user trials will be carried out under the WP7 work. It is expected that D8.3 supposes the ethical guide for the development of these evaluations.

Of course, this deliverable has a close relation to the others belonging to WP8, especially with D8.1. With regards to this deliverable, its main aim was to establish a general framework for the ethical and data privacy issues as well as to collect the legislation of the countries that held personal data from the users. Based on these legislations and on the data protection plan described in D8.1, the deliverable D8.3 aims to elaborate a plan for the user trials and for the interaction with the HERMES system. Specifically, the idea of this deliverable is to extent the information pointed out in the point five: HERMES at runtime, in the D8.1.

The deliverable is structured as follows:
Chapter 2 gives an overview about the ethical advisory board: profile of the advisors, tasks, planning, etc. In section 3 a very brief summary about the ethical issues in the countries involved in the project is provided. The next chapter provides information regarding the ethical documents which are also shown in the annexes. A table summarizing possible ethical risks in live-operations as well as the way in which these risks will be solved appears in section 5. The scenarios in chapter 6 provide some examples in the real life about the risks shown in the previous section. The final idea is that the HERMES system will be a system accessible for people of different ages, cultures and genders, as explained in chapter 7. The following chapter addresses the ethical concerns will arise in the trials. In the next section the comments about this deliverable by the Matia/Ingema/Hurkoa Ethical Committee and the external Ethical Advisory Board are shown. Finally, some conclusions are drawn up.

# 2. HERMES Ethical Advisory Board

Due to the ethical implications of the HERMES project in both the user trials and in the future, when HERMES is installed at home, the consortium of the project needs to be assessed also by an External Ethical Advisory Board. The main goals are to advise the consortium on ethical and privacy issues that may arise in the project and to approve the research activities involving human participants before them.

Advice on a European level will be provided by:

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## *2.1 Profile*

Dr. Antonio Casado da Rocha, PhD, is a Research Fellow at the Department of Philosophy of Values, University of the Basque Country at San Sebastian (Spain), and serves as Secretary of the Ethics Committee in this city's hospital. His main interests are in healthcare, research and environmental ethics. He has published reviews, commentaries and articles on these topics in journals such as *Bioethics* and *The American Journal of Bioethics*, and has authored a book length introduction to medical ethics in Spanish (*Bioética para legos*. Madrid/México: Plaza & Valdés, 2008), with special emphasis on the role of the patients and lay participants in the healthcare relationship. At the University of the Basque Country he works within the research group on Information, Autonomy, and Systems (IAS) and has taken part in several research projects. Website: www.ehu.es/ias-research/casado/.

Dr. Marjo Rauhala (PhD, MSSc., BA) is an ethicist and social scientist whose current work includes research in the ethical aspects of market barriers in introducing new technologies in the lives of older people (Project "ICT and Ageing"). Rauhala has cooperated as a researcher in European Union and national projects in the areas of ethics and assistive technology design; policy research regarding social inclusion and participation of older people and disabled people; and ethics in the design and implementation of assistive technology in care for persons with dementia. She shaped and conducted ethical peer review in the project "Friendly Restroom" within the FP5 Quality of Life Program, and is currently member of the ethical advisory boards of two FP7 projects. Rauhala's research centers on ethical questions that are encountered in the settings of everyday technology research and development work. As an approach to studying ethics in practice, she combines methods of empirical social research and academic ethics.

## *2.2 Tasks assigned*

The main task of the ethical advisors 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 a individual and as a social being:
    - Safety, well-being and rights of the participants
    - Scientific validity of the research
    - Fair selection of the subjects for the user trials in the project. This is a justice principle.
    - Favorable proportion risk vs. no risk in the user trials and in the interaction with the system. This is related to the nonmaleficience principle.
    - Considerations about the user's authenticity right
    - Independent evaluation with each user
    - Informed consent

- Respect to the participants

This deliverable D8.3 is expected by month 18 just previous to the start of the user trials. As specified in Task 8.1: "Prior to any user contact, it is mandatory that the test plan is confirmed through a review of the ethical advisory board" For this reason, the first task of the members is to review this deliverable and of course, to give feedback to the partners about the way in which privacy should be maintained throughout the trials.

Before starting the second user trial, a meeting between Ingema, Cure and the two members of the Ethical Advisory Board will be scheduled. The objective is more or less the same: to explain how we plan to carry out the second user trial and then to get their feedback about this issue.

At these meetings ethical issues about how HERMES must work once installed at user's home will be dealt with. This is a critical aspect to the implications in the design. That means there are some possible privacy and security problems that can be solved if they are taken into account in the design of HERMES (e.g. the privacy levels described in chapter 5). Also, at the end of the project a specific meeting will be held to deal with these issues.

## *2.3 Work planning*

At the beginning, it was planned to invite the external ethical advisors to Brussels in order to explain the ethical issues and get their feedback at a face-to-face meeting. It was not possible to celebrate this meeting due to agenda problems and time constraints. Instead of the meeting, one partner of the project in Vienna and another in San Sebastián have contacted with them. The Internal Ethical Advisor has sent them the deliverable and answered the questions about the project, the ethical issues and so on. Together with the deliverable, an evaluation template of it has been sent. The aim of this template is to collect the reviewers' comments regarding: the changes that are required to make in the evaluation plan, the information contained in the deliverable and, finally, whether they accept or not the actions with the users from the ethical point of view.

In the future, the following meetings or information exchange are planned as follows:

- Information exchange: after the first user trial (November 2009), both partners of the project involved in the users' evaluations will exchange information with the external ethics board about how these evaluations have been carried out, whether any ethical problems have arisen and how we have solved them, etc. The aim is to be able to identify possible failures in the process and to be able to correct and avoid them in the next user trial.
- Before the second user trial (month 28 or 29), a face-to-face meeting is planned to explain the way in which the ethical issues will be addressed.
- Before the end of the project (month 31-32) a meeting in which ethical recommendations about how HERMES should work after the project will be held.

# 3. Ethical issues management in each country involved in the project

In this point how each partner manages the ethical issues should be specified. Though this topic was already commented in D8.1, in this deliverable is expected to find a brief summary about it. The aim is to give an overview to the ethical advisory board and to the Matia/Ingema/Hurkoa Ethical Committee, who did not review the D8.1.

HERMES will carefully consider the ethical aspects of the project with the aim to ensure at every moment and in every situation the adequate protection of the data privacy and the personal rights of the users. 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 organisations participating in the project and in general the limitations and regulations that must be applied to every project activity: research, development, testing and evaluation.

***General ethical framework***. Persons and organisations participating in the project will guide their activities by means of the following four principles:

1. Nonmaleficence. The study and general operation of the device should not harm the participant, or put him or her under unacceptable risk (this includes risks to privacy).
2. Beneficence. The study and general operation of the 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).
3. Justice. The study and general operation of the 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 fair selection of the subjects for the user trials). Benefits of the study will be shared with the involved communities (this includes publication of the results of the study).
4. Respect for autonomy. With the general aim of promoting the participants' cognitive and functional abilities, participation in the study and in the general operation of the device should be based upon a process of informed consent, and the participants right to control his or her personal information will be respected at all times (this includes issues of confidentiality and data security).

Research and development in the HERMES project will be conducted in Spain, Austria, United Kingdom, Greece, Italy and Israel. In addition, field testing and evaluation will be performed in Donostia-San Sebastián (Spain) and in Vienna (Austria). It is planned that part of the results will be transferred to non-European countries, specifically Israel; but, in any case, no transfer of personal data will be performed.

**Spanish legislation:**

- Spanish Organic Law 15/1999 of 13 December on the Protection of Personal Data (LOPD 15/1999). Specially the legislation concerning the following articles:
    - Art. 4: Quality of the data
    - Art. 5: Right of information in the collection of data
    - Art. 9: Data security
    - Art 10: Duty of secrecy
    - Art. 15: Right of access
    - Art. 16: Right of rectification or cancellation

**Greek legislation**

- "Individual protection for personal data processing - 2472/1997 Greek law"

- 'Hellenic Data Protection Authority' (2000)

**Austrian legislation**

- Privacy law - Datenschutzgesetz 2000 or in short DSG 2000 (long name: Bundesgesetz über den Schutz personenbezogener Daten) [18]
- Data security law for medical information - Gesundheitstelematikgesetz or in short GTelG (long name: Bundesgesetz betreffend Datensicherheitsmaßnahmen beim elektronischen Verkehr mit Gesundheitsdaten und Einrichtung eines Informationsmanagement, Stammfassung BGBl. I Nr. 179/2004

**Israeli legislation**

- The Protection of Privacy Law 5741-1981, 1011 Laws of the State of Israel 128, amended by the Protection of Privacy Law (Amendment) 5745-1985
- The Computer Law of 1995
- The Genetic Information Law of 2000.

As British and Italian legislation were no mentioned in D8.1, they are described in detail in this section.

**British legislation**

It will fulfil all the requirements stated by the Data Protection Parliament Act 1998 that intends to guarantee and protect the public liberties and fundamental rights of natural persons, and in particular their personal and family privacy, with regard to the processing of personal data. The data protection principles gathered in this act are the following:

1. Personal data shall be processed fairly and lawfully and, in particular, shall not be processed unless:
    a. At least one of the conditions in Schedule 2 is met, and
    b. In the case of sensitive personal data, at least one of the conditions in Schedule 3 is also met (*see below for details of Schedule 3*)

2. Personal data shall be obtained only for one or more specified and lawful purposes, and shall not be further processed in any manner incompatible with that purpose or those purposes.

3. Personal data shall be adequate, relevant and not excessive in relation to the purpose or purposes for which they are processed.

4. Personal data shall be accurate and, where necessary, kept up to date.

5. Personal data processed for any purpose or purposes shall not be kept for longer than is necessary for that purpose or those purposes.

6. Personal data shall be processed in accordance with the rights of data subjects under this Act.

7. Appropriate technical and organisational measures shall be taken against unauthorised or unlawful processing of personal data and against accidental loss or destruction of, or damage to, personal data.

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

And, among the *conditions relevant for the processing of sensitive personal data*, gathered under the Schedule 3 of the act, some of the most relevant are the following:

1. The data subject has given his explicit consent to the processing of the personal data.

2. The processing is necessary for the purposes of exercising or performing any right or obligation which is conferred or imposed by law on the data controller in connection with employment.

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

This law shall apply to personal data recorded on a physical support which makes them capable of processing and to any type of subsequent use of such data by the public and private sectors. Some important information regarding the British Data Protection Act 1998 that applies to HERMES:

*Section 7: Right of access to personal data*

1. Subject to the following provisions of this section and to sections 8 and 9, an individual is entitled:
   (a) to be informed by any data controller whether personal data of which that individual is the data subject are being processed by or on behalf of that data controller,
   (b) if that is the case, to be given by the data controller a description of:
      i. the personal data of which that individual is the data subject,
      ii. the purposes for which they are being or are to be processed, and
      iii. the recipients or classes of recipients to whom they are or may be disclosed,
   (c) to have communicated to him in an intelligible form:
      i. the information constituting any personal data of which that individual is the data subject, and
      ii. any information available to the data controller as to the source of those data, and
   (d) where the processing by automatic means of personal data of which that individual is the data subject for the purpose of evaluating matters relating to him such as, for example, his performance at work, his creditworthiness, his

reliability or his conduct, has constituted or is likely to constitute the sole basis for any decision significantly affecting him, to be informed by the data controller of the logic involved in that decision-taking.

*Section 10: Right to prevent processing likely to cause damage or distress*

1. An individual is entitled at any time by notice in writing to a data controller to require the data controller at the end of such period as is reasonable in the circumstances to cease, or not to begin, processing, or processing for a specified purpose or in a specified manner, any personal data in respect of which he is the data subject, on the ground that, for specified reasons:
   (a) the processing of those data or their processing for that purpose or in that manner is causing or is likely
   (b) to cause substantial damage or substantial distress to him or to another, and
   (c) that damage or distress is or would be unwarranted.

*Section 33: Research, history and statistics*

1. In this section— "research purposes" includes statistical or historical purposes; "the relevant conditions", in relation to any processing of personal data, means the conditions:
   (a) that the data are not processed to support measures or decisions with respect to particular individuals, and
   (b) that the data are not processed in such a way that substantial damage or substantial distress is, or is likely to be, caused to any data subject.

2. For the purposes of the second data protection principle, the further processing of personal data only for research purposes in compliance with the relevant conditions is not to be regarded as incompatible with the purposes for which they were obtained.

3. Personal data which are processed only for research purposes in compliance with the relevant conditions may, notwithstanding the fifth data protection principle, be kept indefinitely.

4. Personal data which are processed only for research purposes are exempt from section 7 if:
   (a) they are processed in compliance with the relevant conditions, and
   (b) the results of the research or any resulting statistics are not made available in a form which identifies data subjects or any of them.

5. For the purposes of subsections (2) to (4) personal data are not to be treated as processed otherwise than for research purposes merely because the data are disclosed:
   (a) to any person, for research purposes only,
   (b) to the data subject or a person acting on his behalf,
   (c) at the request, or with the consent, of the data subject or a person acting on his behalf, or
   (d) in circumstances in which the person making the disclosure has reasonable grounds for believing that the disclosure falls within paragraph (a), (b) or (c).

**Italian legislation**

The “Code of conduct and professional practice applying to processing of personal data for statistical and scientific purposes” will be followed. The provisions of this Code of conduct and professional practice are aimed at reconciling the individual's fundamental rights and freedoms, in particular the right to personal data protection and the right to privacy, with the requirements of statistics and scientific research as deriving from the principle of freedom of research set forth in the Constitution, which is a precondition for scientific development, improvement of individuals' life-styles, and the growth of a democratic society. Researchers working, whether alone or jointly with others, within universities, research bodies and institutions, and scientific societies, shall abide by this Code in all stages of processing personal data for statistical and/or scientific purposes regardless of whether the respective bodies and scientific societies have undersigned this Code. Some of the articles of this Code applied to HERMES are the following:

*Article 4. Identificability of Data Subjects*

1. For the purpose of applying this Code,
a) a data subject shall be considered to be identifiable if a significantly likely association can be established - by using reasonable means - between the combination of the modalities of the variables relating to a statistical unit and the identification data of the latter unit;
c) in case of communication and/or dissemination, a data subject may be regarded as not identifiable if the identification risk - in terms of likelihood of identifying said data subject by having regard to the data that have been communicated and/or disseminated - is such that the means possibly required to effect identification are to be considered disproportionate compared with the (risk of) damage resulting therefrom to the data subjects' rights, also in the light of the benefit(s) that might be achieved.

*Article 8. Data Communication and Dissemination*

1. It shall be allowed to disseminate statistical results, also by publishing them, exclusively in aggregated format, or else in a manner preventing data subjects from being identified also based on indirectly identifying data - except where the dissemination concerns public variables.

*Article 9. Processing of Sensitive and Judicial Data*

1. As a rule, sensitive and/or judicial data processed for statistical and/or scientific purposes shall be anonymous.
3. Where the data as per paragraph 1 are contained in lists, registers, and/or databases that are kept with the help of electronic means, they shall be processed by using either encryption techniques or identification codes and/or other solutions that, in the light of the number and type of the processed data, make said data temporarily unintelligible also to those entities that are authorised to access them and allow identifying data subjects only if this is necessary.

*Article 13. Data Collection*

1. The entities referred to in Article 2(1) shall pay specific attention to both selecting the staff in charge of data collection and setting out organisational and methodological arrangements for the survey, in order to ensure compliance with this code and safeguard data subjects' rights.
2. The staff in charge of collection shall abide by both the provisions laid down herein and the instructions received. In particular, they shall
a) disclose their identities and functions and the purposes of collection, also by means of appropriate documents;

b) provide the information as per Section 13 of the decree and Article 6 hereof as well as such other explanations as can allow data subjects to answer adequately and knowledgeably, and refrain from any conduct that might be regarded as deception and/or undue pressure;
c) not collect personal data from the same data subjects at the same time on behalf of several data controllers, except where expressly authorised to do so;
d) timely rectify mistakes and inaccuracies affecting the information gathered in the course of data collection; and
e) take special care in collecting sensitive and/or judicial data.

*Article 14. Data Retention*

1. Pursuant to Section 99 of the decree, personal data may be retained for statistical or scientific purposes also for longer than is necessary to achieve the purposes for which they have been collected and/or subsequently processed. […]

*Article 17. Rules of Conduct*

1. Data processors and persons in charge of the processing that can lawfully access the personal data processed for statistical and/or scientific purposes on grounds related to their work and/or research(es) shall also abide by the following provisions:
a) personal data may only be used for the purposes set forth in the research project as per Article 3 hereof;
b) personal data must be kept in such a manner as to prevent their loss, removal and/or any other use that is not compliant with both the laws and the instructions received;
c) non-publicly available personal data and news that become known in the course of performing statistical activities and/or activities that are instrumental thereto may not be disseminated or used in whatever manner for one's own or another's private purposes;
d) any and all activities performed shall be adequately documented;
e) the professional skills related to personal data protection shall be continuously adjusted to methodological and technological evolution;
f) communication and dissemination of statistical results shall be fostered by having regard to the informational requirements of both the scientific community and public opinion in compliance with personal data protection legislation;
g) any and all conduct that is not in line with the rules of conduct set out herein shall be immediately reported to either the data processor or the data controller.

# 4. Ethical documents

The different documents needed before starting the user trials are explained in this chapter and attached in the annexes.

## *4.1 Informed Consent*

Informed consent is the process by which a participant will be fully informed about the research in which he/she is going to participate. It originates from the legal and ethical right that the participant has to direct 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 subject has the right to be involved in the research process.

In order to involve a human being as a participant in research, the researcher will obtain the legally effective informed consent of the participant or the participant's legally authorized representative. In HERMES the target group have the cognitive capabilities preserved, so they will sign the consent by themselves.

The information given to the participant or the representative will be in understandable language to the participant or the representative person. No informed consent, whether 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.

Also, appropriate and adequate information (e.g. the nature, duration, and purpose of the experiment; 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 quit the testing at any point) shall be given in order to ensure informed consent. A model consent form in English has been appended to this document (Annex 1). This was the consent used in one specific task with end users in the project. But each time the participants have to come for a new task the procedure part is adapted to this new task. This consent has been developed following the laws: Organic Law on Protection of Personal Data (LOPD 15/1999); Law 41-2002 of the Patient's Autonomy; Biomedical Law 14-2007. All test partners will use a translated version in order to ensure informed consent and integrity of the participants.

Participants will receive a copy of the Inform Consent and the Information letter.

## *4.2 Information letter*

The aim of this document is to provide the necessary information about the study in order to guarantee that the participant has enough information about the study and s/he can take the adequate decision about her/his participation on it. The document summarizes the main information with regard to the project: objectives, methods, participants, etc. The information letter in English can be found in Annex 2, and also it will be translated by the test partners into their own languages.

Both the informed consent and the information letter were the ones developed for one concrete task in WP2. Of course, every time the user participates, he has to sign a new consent. The only difference between this consent and the one presented here is to be found in the "Procedure" part, which is updated with the actions, objectives, etc., required each time.

## *4.3 Ethics Committee approval*

As explained in D8.1, Ingema has an official approval for the HERMES project by their local ethical committee (Matia/Ingema/Hurkoa ethical committee). Ingema as part of the MATIA group has, according to the Spanish law [223/2004], a Research Ethics Committee that has to approve all the research projects involving human participants. This Ethical Committee was accredited by Resolution of the Basque Health Department (BOVP 18th July 1997). This

Committee guarantees the best quality of social, psychological, and public health attention to elderly people and the fundamental ethical principles required for a clinical research on human beings. This Committee respects the criteria of Good Clinical Practice in Investigation and Helsinki (World Medical Association Declaration of Helsinki) and Oviedo Agreements.

# 5. HERMES working

This point refers to the way in which HERMES will keep the safety and privacy of the users when it will be installed at the user's home. The first draft is the table in which the scenarios and the possible conflictive ethical issues as well as their possible solution are specified. This table will be continuously readapted along the project and shown in this point.

The main point that should be improved is to find the necessary measures to protect the privacy of people interacting with the system in live operations and to ensure the ethical soundness of the system, but also balancing this with usability of taken steps.

A number of ethical 'risks' during live operations of deployed HERMES systems (beyond 2010) have been identified and are addressed within the project. These elements are described in the ethical risk & remedy table (Table 1).

In this sense, some actions have been identified by the consortium in order to keep the privacy when HERMES system will be implemented. These are the main actions:

1. *Restricted access* (username/password) for each user in multi-user operation modes.

2. *Encryption* as a per-default setting for storage of personal information.

3. *Scenario-based privacy levels* that are selected by the user.
   The "privacy level 0" is the minimum level that can be found. And the privacy level 2 is the maximum level can be specified. But the maximum level of privacy depends on the scenario. In general, in the scenarios in which consent is required, the way in which this is given is the following: the person is recorded by HERMES system in both video and audio reading a text with a predefined text in which he accepts to be recorded by HERMES. The system recognizes some concrete words in the message and it knows that a person can be recorded. If one person does not record this message, HERMES does not recognize neither his voice nor his face, and he is not recorded.

The following table summarizes the possible ethical risks and also their remedies. Number 5, which always appears in the column: "Impact of Breach", means that the greatest possibility of reaching that risk is always five. And the number which appears before the number 5 is an indication of the possibility of reaching the highest risk impact. So the nearer the number is to 5 the greater the possibility of reaching this risk.

***Table 1: Risk and Remedy Table***

| RISK | RISK OF BREACH | IMPACT OF BREACH | REMEDY |
|---|---|---|---|

| | | | |
|---|---|---|---|
| **Two people both using the same HERMES system**<br><br>**At risk:**<br>The privacy of the partner | Respect for partner's **privacy** due to shared use of the system | 4/5 | The HERMES system is a personal system; however it is not only designed to be used by people living alone. Instead, user requirements analysis actually indicated that the chances that memory supports are used is higher in shared households.<br><br>With two partners living in one home a working solution is to have separate accounts, each kept private through a login with username/password. Although more usable solutions are being investigated, this is beyond the scope of the project to address this to full extent in the HERMES project. |
| **Recording someone at home**<br><br>**At risk:**<br>The privacy of the visitor | Respect for visitor **privacy** | 4/5 | The privacy of someone visiting the home is covered through consent. The responsibility of this consent lies with the user of HERMES. However, the system itself proactively addresses the issue by announcing its function upon entrance of a new visitor. When a visitor is known, the system can load the according privacy level depending on consent being available or not.<br><br>The following privacy levels can be used:<br><br>Privacy level 0: the persons that usually go to the user's home give their consent for being recorded in audio and video. When these persons enter, HERMES recognizes their faces and voices and records them in audio and video.<br><br>Privacy level 1: the persons that usually go to the user's home give their consent for being recorded in audio but not in video. When these persons enter, HERMES recognizes their voices and records them in audio but not in video.<br><br>Privacy level 2: the persons that usually go to the user's home don't give their consent for being recorded. So the user takes some notes after the visit. |

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| **Recording audio/video outside home**<br><br>**At risk:**<br>Privacy of the conversation partner | Respect for conversation partner's **privacy** | 2/5 | Whereas recording inside the home could be hidden out-of-sight, the recording in outdoor environments typically requires an explicit gesture by the user which will raise questions from the conversation partner. That is, in order for the user to get acceptable audio quality from recordings, the user will have to place the mobile device in a visible position between the speakers. In that sense, privacy risks are slightly mitigated through explicit action (comp. taking pictures of a conversation partner with a digital camera is usually not accompanied with a signed consent form. But in this scenario, consent should be requested verbally).<br><br>The following user-set privacy levels can be used to further increase privacy for outdoor recordings:<br><br>Privacy level 0: the persons that talk to the user outside home give their consent for being recorded in audio and video. When the faces and voices of these persons are recognized by HERMES, the system records them.<br><br>Privacy level 1: the persons that talk to the user outdoors give their consent for being recorded in audio, but not in video. When these persons talk, HERMES recognizes their voices and records them in audio but not in video.<br><br>Privacy level 2: the persons that usually talk to the user outside home don't give their consent for being recorded. So the user takes some notes in his PDA after the conversation. |

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| **Reminder at home / mobile**<br><br>**At risk:**<br>Dignity of the users | Respect the dignity of the person | 3/5 | A reminder can be very helpful at times, but can also be annoying when the user is concentrated on something else, and be embarrassing in certain situations where the user is not alone, either at home or outdoor.<br><br>The user can therefore set a number of privacy rules to change the way that reminders are presented to the user.<br><br>Privacy level 0: The user always chooses to receive auditory and visual alerts about her appointments.<br><br>Privacy level 1: The user chooses to receive auditory and visual alerts about her appointments when she is alone but only an auditory alarm when she is with someone else.<br><br>Privacy level 2: The user chooses to receive auditory and visual alerts about her appointments when she is alone but not to receive any kind of alerts when she is accompanied. |
| **Shared use of the HERMES Past application**<br><br>**At risk:**<br>Privacy of the other persons that appear in the recordings | Respect the privacy of each user of the same device | 1/5 | All the persons who have given their consent to be recorded by HERMES system have also given their consent to let the user have a look at these photographs with other friends and relatives.<br><br>The user has access to their recordings when he or she is with someone else. |

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| **Cognitive games**<br><br>**At risk:**<br>The possibility to play on-line cognitive games | Confidentiality of cognitive health status | 5/5 | Cognitive games can be played alone or together with other people using an internet connection. However, it can be argued that the opponent can get access to details about the cognitive status of the user through the online game platform – the chances of the risk occurring are low but since cognitive training data can be seen as medical data (even if no diagnosis can be provided by the system itself) this would pose a critical situation.<br><br>The user can therefore set the following privacy levels:<br><br>Privacy level 0: the user can play cognitive games with everyone who is on-line<br><br>Privacy level 1: the user can play cognitive games only with the persons who have given their consent for this kind of gaming. The IDs of these persons are stored in HERMES database<br><br>Privacy level 2: the user can not play cognitive games on-line<br><br>In addition, the HERMES system does not in any way require an internet connection present after implementation. When the system runs stand-alone, this risk is reduced. |

# 6. HERMES scenarios: ethical approach

In order to make clear the point 5 some of the HERMES scenarios have been selected and explained here. The difference between these scenarios and the ones shown in D2.3 will be the underlying approach. In these scenarios the ethical issues are reflected.

Luis and Felisa are a couple, 65 years-old each, who were married and have lived together for 35 years. Luis is a retired electrician and Felisa is a housewife. She used to work in a printer factory, but withdraw the job after they got married to take care of the children. They have raised 3 children, Rosa, Javier and Elena, who are respectively 35, 33 and 30 years old. The three of them are already independent, living in their own homes with their respective couples.

During the last years, especially after Luis got retired and children left home, a combination of lack of activity and responsibilities has lead to occasional forgetfulness in daily life, like living the lights on or forgetting the keys inside home. Also, Felisa is Type I diabetic, so she needs to maintain a strict routine in taking her medication, but sometimes she forgets it, which has led to specific health problems regarding to her pathology (sudden glucose decreases or increases, and so on).

Their son Javier, usually the one who is more up-to-date with technological issues, has bought them HERMES system, which is thought to help each of them with their memory problems, including helping them with their appointments with the doctor, relatives, etc. It is composed of a PDA and some devices to be installed at home. It is a personalized system for each of them, because they can configure their own level of privacy. However, they trust each other and have decided to predefine the same level of privacy (an option that may be changed if they want). Also, their relatives and closest friends have explicitly agreed to consent to be recorded by both audio and video means, and this acceptance have been recorded by the system; hence, there is a Hermes for Luis, and another Hermes for Felisa in the same technological platform.

Since they have their own Hermes, but only one computer, they initially thought to just share it. However, it is already enough for each of them to remember their own appointments (specially for Felisa, with her medication), so, in order to avoid problems, they decide to configure the system (enter name and password) so each of them can train their own memory with their own personal information, instead of mixing it with the information of the other partner.

Later, they have been taking care of Rosa's children, who are 8 and 3 years old, and this, while making them stay more active, have increased their burden of responsibility to a extent that sometimes make their daily life a little forgetfulness more frequently. Because of this, Luis and Felisa have explained to their relatives that they would like to use Hermes to record the conversations they have when they come at home, in order to remember the details afterwards. Elena makes a joke about it: "*I will have to be very careful about the clothes that I wear when I visit you, I will be on the computer!*". They commit with their relatives to ask them whenever they intend to record anything.

One morning, Felisa has to call the plumber. She receives his visit. Since it is an unusual visit, Hermes does not record anything because Hermes does not have his consent for it. She opens the door; the plumber comes in, and makes a revision of the problems with the toilet. He gives her details about what is broken and what he is going to do. Since this is not a usual visit, after

the plumber leaves her home, Felisa records in the PDA "*the plumber has been here; the toilet was jammed so he needs to come another day with the proper tools; he has promised to be back tomorrow at 10.00 am and to give me the bill (please Felisa, don't forget to ask him for the bill). Another 24 hours with the toilet broken!*". In this way, Felisa is able to register this properly, and, when she needs to explain her husband what happened during the visit, she can use Hermes to retrieve the information.

Afterwards, she has received a visit from one neighbour. This neighbour has explained her that there is going to be a meeting of all the neighbours of the same community to discuss some issues about repairing the elevator, the roof, etc. Felisa has asked her whether she could record this information in audio so she could remember it later and say it more accurately to her husband. The woman agrees and explains everything in detail, including that the neighbour meeting will be at 7.30 pm the day after.

In the meantime, Luis has gone to visit his former co-workers in the facilities of the company he used to work at. He was one of the bosses, so, even if he had good relationships with his former employees, he is embarrassed of his own memory problems, and does not want to appear in front of them as a disabled individual who needs a machine to remember things. Because of that, he has turned off the volume in the HERMES mobile device, but has left the vibration on, so in case he receives an incoming reminder, he can access it without explaining the others that he actually wears a mobile device because he forgets things, and watch it later (the vibration is the same as when someone receives a SMS in his cell phone). In the way back home, he can read the reminders when he is alone. The device reminds him that he has to be in the doctor's at 10 am the day after.

The day after, while Felisa is attending the plumber again, Luis goes to the doctor. He has been suffering some cardiac problems, so the doctor provides him a list of medications he should take, and medication taking times. Luis asks the doctor if he could record the information, but the doctor does not think this is a good idea, so he kindly asks him not to record anything. After getting out of the doctor's, he records this information, since the writing of the doctor's prescription is impossible to understand (the calligraphy is not very good…), and because he wants to remember all the details.

Luis goes back home, and notices that he has forgotten the keys. Fortunately, Luisa is at home and she opens the door. They have lunch, and, afterwards, they decide to play some cognitive games in Hermes. Luis sets his privacy level in the lowest level, since he feels prepared to share games and game scores with any individual who is on-line at the moment. Luis plays with people from Austria, Greece, UK and from the rest of Spain. On the contrary, Felisa is just starting playing games, and she prefers to play only with relatives and close friends, so she sets up the privacy of Hermes cognitive games at a higher level, so the only people who can see her scores and profile details are the one she has allowed it to (e.g. relatives and friends) and whose ID are stored in HERMES database.

# 7. HERMES: a solution for everybody

HERMES should be accessible for people of different age groups (elderly people and very old people – over 85 years-old), both genders and different cultures. And also, it should provide all of them with the same opportunities. It depends on the group the person is that s/he may need some functionalities or others. We have tried to cover this issue by means of a device which can be customized and personally configured. If we develop a modularized device, each person is able to choose the functionalities s/he needs in the way s/he prefers. For example, the cognitive game module is totally personalized as the user plays with his information. Of course, the more complex your everyday tasks are, the more difficult the games are. Another way of customizing the cognitive games is to adapt their difficulty to the user's cognitive level.

## *7.1 People of different age groups*

Ageing is associated with a tendency to increased heterogeneity related to a wide variety of psychological, social, biological, and other characteristics. For this reason, special attention has been given to developing a system that will provide the same opportunities, in terms of functionalities, usability and so on, for all the potential users.

From the point of view of equality, life course experiences (and sociocultural contexts that sustain and bolster exposure to these life course experiences) can give rise to differences between subjects in the use of technology. Nevertheless, technology can also help to minimize sociocultural differences between individuals and groups if accessibility and usability variables are observed. In the process of HERMES development, differences in attitudes towards technology and the use of it have been analyzed. By means of questionnaires, interviews and other instruments as described in D2.1, we have asked elderly people about their attitudes, preferences, etc, in order to find the most usable tool for them. If we achieve this objective, to get the easiest way to use technology, the difference in the use of technology due to age (the younger the people are, the more accustomed they are to technology) will disappear. These considerations are relevant since previous studies have shown that attitudes to technology are modifiable for people of all age groups depending on their experiences (Czaja & Shark, 1998), especially taking into account that in the user needs and requirements study, it was found that older users are willing to use accessible and supportive forms of technology.

In the HERMES project we will try to get elderly people and also very elderly people (over 85 years-old) to do the user trials. Also, at the end of the project a comparison between the results in the user trials in these groups will be made.

## *7.2 People of different gender*

Increased heterogeneity throughout the lifespan of a person is strongly related with gender differences. Gender differences are one of the reasons for strong inter- and intragroups

differences in ageing. As an example, an older woman has a greater involvement in family roles, and some of the implications of this commitment are:

- Achievement of wider and stronger social networks,
- Competition with their role as employee which often results in a history of discontinuous work and a lesser degree of technical abilities, including experience with ICTs.

With respect to the obligations of a housewife, women also present financial constraints. Although there are Social Security benefits for elderly people, later-life status involves a complex set of relationships. In these relationships, some variables play a crucial role such as employment history, social status and life events such as disability and widowhood. Regarding this, it is necessary to take into account the fact that the later-life economic status gives rise to different groups of elderly people. These groups have access to different social and sanitary resources and, of course, some, but not all, have access to technology (Crystal & Waehrer, 1996).

Relatively few gender differences in attitudes to technology have been found in the literature. Czaja & Shark (1998), outlined that women experienced a greater increase than men in comfort with computers following task experience. However, women also found computers to be more dehumanizing following task experience. Moreover, in this study it was found that older women are as receptive to computer technology as younger women. In HERMES, usability and accessibility requirements have been covered in such a way that gender differences in the usage of the devices are avoided. One way to avoid these differences will be to try to get people for the user trials from both genders.

With respect to the gender, some actions have been carried out or will be done in this project:

- Increasing the participation of female researchers in the project
- Try to get an equal number of males and females participating in the user trials. Up to now, this action has been followed and in the tasks with user involvement in the WP2 (e.g. questionnaires, memory assessment, etc), a greater number of females in the different countries (Spain and Austria) have participated.
- The study of the different impact that HERMES project could have on the two genders will be taken into account. One of the parts of the questionnaire that will be administered at the end of the user trials and will aim to collect the impact in both genders. After that, the results will be analyzed and, if there are differences between two genders, some actions must be followed in order to minimize them. The actions will be specified later because they depend on the results found (e.g. actions in the functionalities, in the design…).
- Language and images: The written language is equal for both in English as in the original languages of the partners' countries. Also, the use of images that appear in all documents is equal for both genders.

## *7.3 People from different cultures*

People from different cultures may have different needs, opinions, history of use with the technology, etc. As HERMES is a European project, its aim is to offer a new innovative system usable for people of different countries. This issue is covered in this project, since mainly two partners carry out the evaluations with the users and then they will make a comparison of the results. For example, in the scenarios assessment, different focus groups were held in Spain and

Austria, and then the results were compared. The main conclusion was that needs, preferences and other variables assessed in these focus group (see D2.3 for more information), are very similar in the two countries.

Anyway, after the first and the second user trial, a similar analysis comparing the results in the two countries will be done. If important differences arise a plan to minimize these differences and to make accessible HERMES system for the users in San Sebastian and Vienna will be developed.

# 8. Ethics in practice: the first and second user trial

The way in which the partners who work with the end users in the trials and also the partners who use the information obtained from these trials will be agreed on and specified in this deliverable.

User-centred design procedures included in the HERMES evaluation protect user rights from the start of the project until its end, 1) by including usability, learnability, acceptability and friendliness of the technologies developed, and 2) also by including evaluation procedures with the users involved. User-system interaction will be evaluated in order to ensure the most usable system to respond to real user needs, ensuring adequate privacy and safety of the participants.

The HERMES system uses very personal data; these data are intended for use in the private domain and, as such, we strive to carry out tests with personal information. Usability evaluations of usage contexts, including installation of the HERMES system prototype at participants' homes, imply a higher level of user privacy. Nevertheless, as has been pointed out before in this document, the personal data collected will always be relevant and not excessive in accordance with the scope and purposes of the project. Privacy will be ensured through the procedures described in this deliverable.

Users in these phases (first and second prototype) will be recruited from the pool of users generated throughout HERMES requirement analysis study last year. In Spain, there are 15 people in this group and it is planed to try to get at least 12-13 of them for the first user trial. In Vienna, 12-16 subjects will participate in the first trial. In order to be included in the user trials, potential HERMES end users have to meet the special inclusion requirements: age over 60 years old, AAMI (Age Associated Memory Impairment) or MCI (Mild Cognitive Impairment) diagnosis, not suffering from any severe sensorial and/or motor problems and living independently in their own homes. It is important that the recruitment of the participants should not discriminate potential users. The processing of the data subjects will be carried out with appropriate safeguards for the rights and freedoms of the participants, including the explanation of the project's procedures and the signature of a consent form.

At the time of reviewing the deliverable, D8.3 a copy of the deliverable, D7.1 was given to the ethical advisors in order to clarify the user trials for them. But also, one part of that deliverable has been copied below to summarize the main courses of actions to be taken with the end users.

## *8.1 First user trial (July-September 2009)*

The aim of the first user evaluation is to assess basic factors like usability, learnability and also acceptability and user experience. The HERMES first user trial will be based on the HERMES first prototype and will support:

- **HERMES MyPast (offline speech-processing)**. HERMES MyPast in its final version will support end users in capturing bits of their lives. The application relies on sensory input coming from microphones and video cameras. The start of the recording can happen automatically (relying on sensory information) or being triggered manually, depending on the preferences of the user. The same is true for the ending of the recording. Once the recording is finished HERMES automatically starts with the post processing of the newly acquired data. To retrieve data from HERMES, the user is provided with different search possibilities: names, time and date intervals, emotions, pictures and keywords. The user has the possibility to retrieve content in different formats: audio only, video only, audio and video and a transcript of the audio. For the first evaluation, we plan to use personal user data (captured last year from each one of the users).
- **HERMES MyCalendar (offline speech-processing, Mobility support).** HERMES MyCalendar in its final version will support end users in planning their lives. MyCalendar enables users to set appointments of different kinds (time based, location based), create to do's and store notes for future use both at home and while on the go. Notes might constitute of recorded audio or typed words. The HERMES PDA will support users on this subject while on the go. To assure consistency with the home based part of the system, HERMES will automatically synchronize the PDA with the home-system. All data concerning future appointments and to do's will be available on both the home based system and the HERMES PDA. This provides the user with access to future appointments wherever s/he might be. Regarding the first prototype, HERMES MyCalendar will support all functionalities described. Again, online speech processing will not be available in the first prototype.
- **HERMES Cognitive Games (one cognitive game implemented)**: HERMES Cognitive Games will provide end users with the possibility to train their cognitive abilities using HERMES. The system serves as a platform allowing the development of different kinds of cognitive games. For the first HERMES prototype one cognitive game will be implemented on the HERMES system.

All these functionalities will be tested in the usability labs, both in Austria and in Spain, according to the evaluation procedures explained in D7.1. While the focus in Austria lies on the general interaction and issues described in section 2 of this document the evaluation of HERMES with Spanish users also includes the speech components. This is because the speech components are being developed with the focus on the Spanish language.

The system will be personalized for each test-subject by populating HERMES with personal data. That means that each test subject will be confronted with his own data only. The HERMES first user trial will also include a field test with the HERMES PDA in real environments (the user will take the PDA with him for some days). Giving the PDA to participants and having them use the device for a week will provide very relevant inputs for the research, since we would get opinions from a real life use, but there are also integrity and security implications as well as specific support needs to be covered by the research teams.

Once the test-subject arrives in the lab s/he will be given explanations about the HERMES prototype. Instructions in the form of tasks will be carried out by test-subjects to a) develop a feeling for the system and its functionalities and b) to assess the technology acceptance, interface complexity, information visualization, game experience, multimodal reminders. Tests will be carried out in the presence of a researcher. This ensures assistance for test-subjects if needed as well as objective observation of test-subjects.

Questionnaires will be kept consistent between the two test locations to compare results and determine differences based on cultural background. The annex 3 of this document lists tasks addressing each HERMES application and the way test-subjects are planned to approach the system.

Additionally interviews with experts in the cognitive domain and care givers will be conducted.

## *8.2 Second user trial (July-October 2010)*

The HERMES second user trial will include improved technologies with respect to the first prototype, and we will deploy the system in its natural context. Personal data obtained through these procedures will be used only for purposes specified in the project and will not be processed in any other manner which is incompatible with these purposes.

As this second trial is expected by the next year there are not so many details about them. Anyway, when we know more about the users' evaluation at this stage we will contact again with the ethical advisory board in order to get their feedback.

Of course, the travel costs from the user's home to the lab are covered by the partner. We are also aware that over a period of three years the target group will participate several times and they will spend a lot of time in HERMES interviews, trials and so on. For this reason, they will receive compensation at the end of the project, which has not yet been determined. The users are informed about these aspects of their participation.

## *8.3 Ethical issues before, during and after the evaluations*

Each time the participants carry out a test, evaluation or another kind of participation, they must give their informed consent, which means that the proposed procedure and its implications will be discussed, and only afterwards will the participant sign the relevant form. As explained before, in the informed consent process the following parts are to be discussed::

- Aim of the study
- Voluntary nature
- Risks/ Benefits
- How the information is stored?
- How the information is encoded?

During the trials, the partners of the project have to share participants' personal and private information. For this reason, they have to follow these principles (as shown in D8.1):

- Before starting the trials it is necessary to prepare the users for the situation. That means, to explain the general objective of the evaluation, the methodology to be carried out, and the participation requested of them. Also, all the doubts should be clarified before starting.
- During the test, people are not obliged to give details about their own lives
- The data will be encrypted or protected with a code during the storage and process
    - Anonymised, as the last year, when people came for the audio and video recordings, with the day, number of session… without names, photographs, identifying numbers.
    - The same codes as the ones given last year (e.g. of a code: HR001//08).
- Only the information contained in annex 3 will be collected. If other information is collected this will not be saved since it is not needed for the purposes or the study.
- Each partner should store the information in a secure way. The database will be sealed from people not involved in the project but working in the organization
- The correspondence between the numerical codes and the user list will be saved into a local encrypted database
- The data will be stored in a locked server and the identification data will be stored separately

One part of the trial is to give the PDA to elderly people. This issue gives rise to some privacy concerns as elderly people should be aware of and responsible for their recordings. For this reason, special attention will be paid to this point when this issue is explained to the users. The partners who interact with them will emphasize that it is not necessary to record other people, and that it is even recommendable not to do so. However, if a participant records a conversation at which other people are present, these parts of the recordings will be deleted by the partners.

In the same way, we must be aware that after the trial:

- It is not allowed to circulate information between partners without anonymization
- Regarding dissemination (paper, publications, presentations…) it is not allowed :
    - Listing of individual cases
    - Description of individual cases
    - Listing, description or identification of the participants by number, by name, or by descriptive information

The data will be saved for five years after the end of the project. After this time, each partner will be responsible for destroying the personal data in his organization.

Whenever a question arises from any partner in the project related with themes about how safeguard the information, share it, or so on, they can ask directly to any partner of Ingema.

# 9. Review of the deliverable

This deliverable has been reviewed by Matia/Ingema/Hurkoa Ethical Committee and by the ethical advisory board. A template for the evaluation of it has been created. The results of this evaluation are presented in the following sections.

## *9.1 Results found in the evaluation made by Matia/Ingema/Hurkoa Ethical Committee*

The deliverable and the way in which the evaluations for the first user trial are going to be carried out have been approved by this Committee. Only one advice has been made about the deliverable: the principles of autonomy, independence, beneficence, nonmaleficence and justice must appear more clearly throughout the document. Also the guarantee of these principles must be a task for the ethical advisory board.

## *9.2 Results found in the evaluation made by Ethical Advisory Board*

The deliverable was sent to the Ethical Advisors at the same time as a template with some questions was delivered in order to obtain some concrete information from them. The first question was:

1. *Do you agree with the tasks assigned and the work plan?*

After some clarifications about the deliverable, both advisors accept the work plan and also the meetings and exchanges as described. One recommendation is to let them know about any new ethical issue which arises in the project and then, include it in a resubmission of the deliverable.

2. *Changes required in the evaluation plan?*

The reviewers do not suggest any relevant changes. Only some minor improvements in the consent form

3. *Is the information contained in the deliverable comprehensive and complete?*

The two reviewers have positively assessed the information in the deliverable in terms of comprehension. Only some minor clarifications have been requested on some points. In the final version of the deliverable these clarifications have been made.

4. *Is any important piece of information missing?*

The information they think is missing is the following:

- In order to make the ethical framework clearer, the 4-principle research has been included. This model is well known and applied in biomedical ethics. While taking into account that the HERMES study is not strictly a clinical one, this 4-principle approach can be successfully adapted to cover most ethical issues associated with this research study.
- Some ethical issues which were already listed in D8.1, and for this reason have not been included again in D8.3.

- It is needed to clarify whether the participants are going to be paid or compensated. Also, it would be better to clarify whether the travel cost to and from the lab will be covered. The answers to these two questions have been included in the consent form

5. *Verdict: to accept or not to accept the actions with the end users?*

The reviewers accept the actions with the end users from the ethical point of view.

They suggest some general questions that we will have to deal with and which are more focused on the future when the project finishes and the user has the system at home. So these aspects will be dealt with at the next meetings, as explained in section 2. Finally, they comment that the ethical documents must be translated and adapted into jurisdictions other than the Spanish one and languages other than English, so that they are consistent with local practices and norms.

Another concern is about the fact that the users are left with the responsibility to inform and to gain the approval of the persons they encounter for using the HERMES system in their presence. This issue will be discussed in the last session between the partners of this project and the ethical advisors, as previously stated in section 2. The users will be briefly trained in why informing others and asking for other people's approval is relevant.

With regard to the language, as the study is not strictly a clinical one and the study participants (and potential users of HERMES) are people over 60 years of age with no cognitive impairment or with a mild, discrete impairment, then they are not necessarily "patients", or "ill people". This should be taken into account, both in the language and legislation present in the document, and in the ethical framework.

The general ethical framework should be grounded on both biomedical research ethics and information technologies ethics. Accordingly, one of the reviewers recommend the 4-principle approach, which is well known and applied in biomedical ethics, but taking into account that the study is not strictly a clinical one, as the partners are not necessarily patients who suffer a disease. However, this 4-principle approach can be successfully adapted to cover most ethical issues associated to this research study.

This approach is usually referred to the work of Beauchamp & Childress (2008), and is based on the following 4 principles, which can be adapted to the HERMES scenario thus:

1. Nonmaleficence.
2. Beneficence.
3. Justice.

It is recommended that a brief mention to these 4 principles is included as a general ethical framework in section 3 of this deliverable, "Ethical issues management in each country involved in the project".

Special attention should be put in the process of translating and adapting the Ethics Documents into jurisdictions other than the Spanish one and languages other than English, so that they are consistent with local practices and norms. The IC document in the Ethical Guide is clearly based on the Spanish context, and it is well grounded on Spanish law, but is it consistent with other countries? If field testing and evaluation will be performed in San Sebastián and in Vienna, it is expected that we will have an IC document for each country, and that both will be adapted to the local particularities.

The Spanish member of the Ethical Advisory Board can only guarantee that the IC document is ethically correct in the Spanish context. According to his best judgement, the planned actions with the end users are correct, and therefore the plan can go on as established.

# 10. Conclusions

Up to now, in the actions carried out with end users: focus group, interviews, etc., no ethical problems have been identified. HERMES trials, and specially the first one which is in one-two months, imply the user involvement and the customization of the system with the real information from each participant. Obviously, ethical and privacy questions arise in these evaluations. The consortium of the HERMES project has elaborated a plan in order to safeguard these issues. The way in which the first user trial will be carried out and the plan to guarantee the ethics have been reviewed by the Matia/Ingema/Hurkoa Ethical Committee and by the ethical advisory board. The first one has approved the action with the user and this deliverable including some minor changes in the information contained. The two members of the ethical advisory board have also approved the deliverable and the actions are going to be carried out with the elderly people.

Due to the fact that some changes may happen during the project (e.g. it is needed to test another component in the trial), this deliverable can be updated in order to include the latest evaluation protocol to be administered and re-submit it as the Ethics Manual-revised form.

This deliverable will be discussed in the next consortium meeting (end of June 2009), in which the Matia/Ingema/Hurkoa Ethical Committee and the members of the ethical advisory board are invited.

Finally, some of the actions that have been mentioned before are summarize in the following points. Besides, some recommendations when the tester will be interacting with the user are provided. The aim is to help the tester to know if he is acting with the user in an ethical way.

- Each partner has to carefully read their country laws.
- Contact for the trials with an equal number of males and females will be tried. Also, people from different ages will be contacted for the user trials.
- The user has to sign the consent before starting the trial. It is not possible to carry out the trial without signing the consent. Besides all the parts of the study must be clear to the user.
- The informed consent and all the documents will use an equal language, without discriminating people for their gender.
- During the trial the tester has to tell to the users that they are not obliged to talk about their own lives.
- The data will be encrypted and protected with a code.
- The user’s personal data has to be safeguard from other people not involved in the project
- In the publications, no personal data will be provided.
- At the end of the trials specific analysis will be made in order to assess if gender and cultural differences (between Vienna and San Sebastian) are found.

- The personal information will be saved for five years after the end of the project. After that, each partner has to destroy it.
- For any question which gives rise during the trials, the partners can consult Ingema about it. Ingema will contact with the External Ethical Advisory Board if it is needed.

# 11. References

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Crystal, S & Waehrer, K. (1996). Later-Life Economic Inequality in Longitudinal Perspective. Journal of Gerontology: Social Sciences 51B, 6, S3O7-S318.

Data Protection Act 1998, Office of Public Sector Information,

Data security law for medical information - Gesundheitstelematikgesetz or in short GTelG (long name: Bundesgesetz betreffend Datensicherheitsmaßnahmen beim elektronischen Verkehr mit Gesundheitsdaten und Einrichtung eines Informationsmanagement, Stammfassung BGBl. I Nr. 179/2004)

Greek Law 2472/1997 on the Protection of Individuals with regard to the Processing of Personal Data - as amended by Laws 2819/2000 and 2915/2000

Ley Orgánica 15/1999, de 13 de diciembre, de Protección de Datos de Carácter Personal.

The Protection of Privacy Law 5741-1981, 1011 Laws of the State of Israel 128, amended by the Protection of Privacy Law (Amendment) 5745-1985

Privacy law - Datenschutzgesetz 2000 or in short DSG 2000 (long name: Bundesgesetz über den Schutz personenbezogener Daten)

World Medical Association Declaration of Helsinki. Ethical principles for medical research involving human subjects. http://www.wma.net/e/policy/pdf/17c.pdf.

# 12. Annexes

## *12.1 Informed Consent*

Title of the project:
Coordinator:
Local Principal Researcher:
Institution:
Financed by:
Project duration:

Participant's name:

The study described in this document is a part of the project called "HERMES-Cognitive Care and Guidance for Active Ageing", financed by the European Commission under the 7th Framework Programme (Consortium Agreement: 216709).

This consent sheet may contain words you do not understand. Please ask either the contact researcher or any professional in the study to explain any word or give any further information. You may take a copy of this consent to think about it or talk to your family before taking a decision. At all times, we try to assure the compliance of the current legislation.

**INTRODUCTION:**
You have been invited to participate in a research study. Before deciding whether you want to participate, we would kindly request that you read this consent carefully. Please ask any questions that may come to your mind in order to make sure you understand all the procedures of the study, including the risks and benefits.

**PURPOSE OF THE STUDY:**
The main aim of the HERMES project is to give support to elderly people of over 60 years of age who present a mild cognitive age-related impairment or not, and also to reduce the progress of that cognitive decline. By means of a device you will be reminded of some things that have happened to you in the past or things that you have to do in the future. Besides, you will be able to stimulate your memory, attention and other cognitive capacities, by means of different games presented in this device. In the document entitled: "Information Page", you will find more information about the purpose of the study.

**PARTICIPANTS IN THE STUDY AND POSSIBLE PARTICIPATION IN IT**
We kindly request your voluntary participation in this research study. This informed consent includes information about the study. We would like to assure that you are perfectly informed about the purpose of our study and what your participation in it implies.

Please ask us to clarify any section in this information document that may be necessary. Please, do not sign if you are not sure that you have understood all the aspects of the study and its objectives, some examples about how HERMES works and so on.

In this part of the study we would like to know the main needs of the elderly, especially those related with memory (e.g. recalling what other people say, recalling the items of the shopping list…). Only if we know what are that people really need, we are able to meet these needs.

The study is totally voluntary. You can give up at any moment without being penalized or losing the benefits.

The participants will be elderly people older than 60 years old with no cognitive impairment or age associated memory impairment.

The travel costs from your home to the lab will be covered by us. At the end of the project you will receive any compensation for your time spent and your valuable input.

**PROCEDURES:**
In this stage of the research, your participation will consist in a memory evaluation made by the Wechsler memory scale. This is an individually applied scale, with an application time ranging from 60 to 90 minutes. It gives the possibility to evaluate together immediate, working or delayed memory. Each of these types of memory is evaluated in two modalities (auditory and visual) with two types of tasks (recall and recognition). It is composed of 11 subtests. The aim of this evaluation is to know better the elderly people memory needs. In the following manner, these needs can be taken into account and their needs would be met by the developed project device.

**RISKS OR INCONVENIENCES**:
No risk or damage is foreseen during the test application.

It is probable that you will not receive any personal benefit for your participation in this study. In any case, the data collected in this study might result in a better knowledge and later intervention for elderly people.

**PRIVACY AND CONFIDENCIALITY:**
We will record your answers to our notes that will not hold any identification of yourself nor it won't be possible to identify yourself later on. In other words, when someone agree to participate in the research, they receive a code-number, and from that moment every personal data are under that code, because of that no one could know to whom the data belongs to. The information will be processed during the analysis of the data obtained and will appear in the project deliverables but again – only in the way that it will not be possible to identify from whom we received the information assuring in every moment the performance of the Spanish Data Protection Organic Law 15/1999, at December the 13th

> "In that law performance we inform you that all personal data that you will provide us by the filling out of the present questionnaire or by the documentation that you will give us to Ingema Foundation will be part of an automated file property of the Foundation, and they will only be used for the management steps and the turnover of the provision of services. Likewise you expressly give us your consent of the data use for the research aims"

The results of this research can be published in scientific magazines or be presented in gerontological sessions, always guaranteeing the complete anonymity.

The authorization for the use and access of the information for the aim of research is totally voluntary. This authorization will be applied to the end of the study unless you cancel it before. In this case we will stop the using of your data. All the data will be destroyed five years after the end of the project.

If you decide to withdraw your consent later on, we ask you to contact the principal researcher of this study and let him know that you are withdrawing from the study.

The principal researcher can be contacted under the following address:

Elena Urdaneta Artola
Fundación Ingema
Usandizaga, 6
20002 San Sebastián
Telephone: 943 224643

From the moment of your withdrawal, your data will not be newly processed in any further phases of the research project. However, it will not be possible to alter already existing published documents or completed project deliverables.

**CONTACT PERSONS**
For further information about your rights as a research participant, or if you are not satisfied with the manner in which this study is being conducted or if you have any questions or sustain any injury during the course of the research or experience any adverse reaction to a study procedure, please contact the principal researcher:

Elena Urdaneta Artola
Fundación Ingema
Usandizaga, 6
20002 San Sebastián
Telf. 943 224643

**CONFIRMATION:**
Your participation in the study is possible only if you sign a stand-alone consent form that would authorize us to use your personal information and the information about your health status. If you do not wish to do so, please do not take part in this study.

I have read the information written in this consent report or it has been adequately read to me. All my questions on this study and my participation have been answered.

Tick one of the following:
☐ I read all the information in this form.
☐ The information in this form was read to me by: .....

All my questions have been answered by: .....

I authorize the use and dissemination of my information to the aforementioned entities and for the above mentioned purposes. The signing of this consent report does not imply the renunciation to any legal right. I voluntarily agree to participate in this research study carried out by Ingema Foundation and the other members of the "HERMES" project. I understand that I am entitled to and will be given a copy of this signed Consent Form.

Name and surname of participant
Date

Signature of participant

Name and surname of the researcher
Date

Signature of the researcher

## *12.2 Information letter for the user*

**AIMS OF THE PROJECT**

The main aim of the HERMES project is to support elderly people older than 60 years old that present a mild cognitive impairment in order to reduce the cognitive decline process, or to support elderly people without cognitive impairment.

Specifically, it is pretended to develop a support device to give help in three fields:

- Helping to remember things happened in the past: Through this application you may remember things that happened to you in the past like, for example, a conversation happened with the physician, who has come to visit you, etc.

- Helping to remember things to do in the future: It is about an advanced calendar that reminds the activities and appointments of the day. For example, you can record your voice in the device saying that you have a medical appointment on May 15th and you have to take your analytic results. The device will record that appointment and will notify it in advance.

- Cognitive training: through games related with personal information (e.g. future appointments, things happened in the past…). For example, one memory exercise could be one in which the device asks you to remember your next week appointments.

The device is mobile so it can be taken outdoors.

**WHO IS THE TARGET GROUP?**

The collective the project is focused on elderly people older than 60 years old with no cognitive impairment or with a mild, discrete impairment in at least one of the next fields: attention and concentration, memory, language, thinking and viso-spatial function.

## EXAMPLES OF WHAT HERMES WILL BE ABLE TO DO

Next, some examples of what HERMES will be able to do are shown. HERMES consists of a mobile device (specifically a PDA, that it is similar to a mobile phone), that you can take outdoors, and a computer that is at the elderly person's house. It is look forward to develop an adapted device to the elderly people's needs and that can be easy to handle it.

***Conversations with the doctor (help to remember things of the past)***

Visiting the doctor: The conversation between you and the doctor will be recorded by a mobile device. This device will be placed in the table between the doctor and you. At the beginning the conversation with the doctor, the elderly person will turn the recorder on and when the conversation ends he will turn it off. When the person wants to remember the conversation, he can search specifically and in a faster way to hear only the interesting section instead of having to hear all the conversation.

***Calendar (help to remember things of the future)***

The elderly person can record future appointments by voice in order to being reminded later. To that end, he has to say the where and when the appointment is in front of the device in loud voice. The person hits a button in the device and records the appointment, once he had finished, he touches again the button and the recording stops.

The appointments will be reminded to the person based in the generating calendar. The person might choose when the device reminds the appointments, in a date (e.g. the day before the appointment, the same day…) in a specific hour (one hour before, two hours before…), or in some cases even depending on his localization (for example, when he is near the drugstore the device reminds to buy the medication).

***Cognitive games based in the personal information (cognitive training)***

There is the possibility to use the recollected data about the person's next appointments to play some cognitive games. In this case the calendar information is the one that will be used.
The system will notify the person that he has not play to cognitive exercises today. The person might do this exercises in which future appointments will be presented. These exercises might have different levels of difficulty. It will be different games, for example:

- To put in order the appointments
- To group the appointments by categories.
- To select the appointments for a concrete day.

## *12.3 Detailed Evaluation Plan for the first user trials*

The following sections describe the evaluation of the different HERMES applications broken down to task level.

## *Evaluation of myPast*

Last year the evaluation of myPast front-end was carried out in Ingema with 8 users. Based on this first evaluation the user interface was drastically altered in order to support the users' further requirements. The following tasks allow us to evaluate the front-end.

**Starting exercises**
1. Please open the application "myPast".
2. Please browse through the application for 1 minute and try to understand what you can do with this application. Think out loud while doing it.

**Tasks**
1. Please go back to the start page
2. Please use the system to find entries that took place between xxx and yyy. (time search)
3. Please find the first entry available in the system that took place at the doctor's office.
4. Please find all entries that are categorized as joyful (emotion search). How many entries do you find in total?
5. Please find the entries associated with the grandchildren Mary and David (photo search). Where was the last entry with David recorded?
6. Please find all entries that took place in the park. How many entries do you find in total?
7. Please find joyful entries between June 2008 and August 2008 where one of the children Angie or Paul is involved. How many entries do you find?

**After each task the following questions will be asked.**
- How well did the system support you in solving the task?
- What would you personally change in the system in order to make it more supportive?

## *Evaluation of the myCalendar Front-End*

**Starting exercises**
1. Please open the application "myCalendar".
2. Please browse through the application for 1 minute and try to understand what you can do with this application. Think out loud while doing it.

**Tasks**
1. Please imagine you have a meeting with a friend next week. You want to save the appointment in HERMES and record a note for it. Can you try to do that?
2. Browse the entries in "myCalendar" and tell me what appointments you have set for the next week. Are there notes added to the appointments?
3. Choose the appointment on the xxx, check the note to it and edit it.
4. Record a new note for the appointment at the xxx.

5. Check if you can find the entries that you set using the HERMES PDA (once the PDA gets near HERMES synchronization should take place)

**After each task the following questions will be asked.**

- How well did the system support you in solving the task?
- What would you personally change in the system in order to make it more supportive?

## *Evaluation of "myCognitiveGame"*

**Starting exercises**

1. Please open the application "myCognitiveGame".
2. Please browse through the application for 1 minute and try to understand what you can do with this application.

**Tasks**

1. Play a few minutes with the application and write or talk out loud your questions about it.

**After each task the following questions will be asked.**

- Compared to the cognitive training you know, how well do you think this system can support you with the training of your cognitive abilities?
- What would you personally change in the system in order to make it more supportive?
- Can you imagine performing your daily cognitive training with HERMES?

## *Evaluation of the HERMES PDA*

For the evaluation of the HERMES PDA we consider giving the PDA to test-subjects and have them use the device for a week. When they come back the PDA will synchronize with the HERMES system automatically and these test-subjects could look for the entries they made using the PDA in the system that is standing in the lab of CURE.

This way we would get personal content for the system that test subjects could search for. Also, we would get opinions from a real life use of the PDA and its functionalities.

Potential tasks for the field-trial of the HERMES PDA:

- Please use this PDA in the following week as often as you can for doing the following things:
    - Whenever you have to write down an appointment use the PDA for it
    - Use the GPS functionality to add a location marker
    - Use the possibility to record an audio note as an addition for an entry
- Whenever you experience troubles give us a call so we can support you.
- Write each day in the evening a sms to xxxxxxxxxx. In the sms please describe your feelings and thoughts towards the HERMES device in a short form – no need for whole sentences. Additionally you can use the possibility of recording audio notes if you want to store lengthy comments and ideas regarding the HERMES system on the device.

## *PostInterview*

After users have carried out all tasks they will be asked to fill out a questionnaire. This questionnaire will consist of the following questions and its purpose is the assessment of acceptability, learnability and user experience.

**Satisfaction with the functionalities (acceptability)**

- Are you satisfied with the functionality provided by the application?
- Have you ever been in a situation, in which you wished for this or a similar functionality?
- In which situations you think could an application like this be useful?

**Satisfaction with the interface (acceptability)**

- Did you encounter problems while using the system?
- Do you think that the interaction with the system is intuitive and predictable? Why or why not?
- What would you like to praise about the system?
- What would you like to criticize about the system?

**Accuracy of the system**

- Did you get the impression that the accuracy of the filter function is very high?
- No matter what answer: What made you get this impression?
- Do you trust the system to give you the right results? Why or why not?

## *Task to be carried out in Ingema focus on the speech technologies*

Besides the tasks commented above, in Spain two tasks will be carried out, in order to get the optimization of the Spanish speech recognition components. Specifically, these tasks are the following ones:

Part1 - Accessing Transcribed and Indexed Audio

- Tutoring and getting feedback on audio playback and reading transcript
- Tutoring and getting feedback on keyword based search
    - Search for single word
    - Stemming (“go” == “going”), accent tolerance
    - Search for a combination of words (implicit AND)
    - Search for <word1> OR <word2> construction
    - Exact phrase search “drink coffee”
    - [Complex constructions: <phrase> OR word1 word2] -- ???
    - Misspelling and “did you mean” interface

Part2: Practice MyPast Search

- Refresh user’s memory about the conversation in general terms
- Quiz: During the conversation you’ve been asked <question>. What have you answered? Use MyPast Speech Search to solve the quiz.

- Present to the user a list of alternative answers. Have him/her searching for the keywords suggested by the list items. Or…
- Have the user searching for the keywords suggested by the <question>

## *Evaluating User Experience*

- Was it fun using the system? Why or why not?
- What would you improve in this system? Why or why not?
- Would you trust this system with your personal photos?
- What are the advantages of such a system compared to a physical photo album? What are the disadvantages? Please mention as many as possible.
- Which information inside your living room would you want to have recorded in such a system? Why?
- Which information would you NOT store in such system? Why?
- If you would own such a system, would you show it to other people? Why or why not?
- Would you browse the system together with other people? Why or why not?