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Care Me For Life

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Deliverable Lead Contractor:

SAG

Main Editors:

Matthias Lindemann SAG

Klaus-Peter Wegge SAG

Approved by:

Cindy Wings ORBIS

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Abstract:

The right to privacy is a human right and an element of various legal traditions which may restrain private party action that threatens the privacy of individuals. This document is related to Privacy of individuals and organizational and technical provisions to achieve and protect it.

This is a key requirement as ethical concerns rise when new technology is introduced to older persons and carers. A detailed analysis regarding issues of privacy, control of personal data and information, confidentiality but also security, will be performed in WP1 prior to implementation and development. Although national differences across Europe will be investigated, focus will be given on the two pilot countries. A project ethics and privacy committee will be set up in WP5 with representatives from each of the trial sites responsible for developing guidelines and codes of practice (documented in deliverable D5.2 Privacy Protection Plan) for use by the project and to also monitor that the guidelines are being properly addressed throughout the project (and beyond it, for issues such as confidentiality of personal data). The ethics and privacy committee will be responsible for all ethical issues related to the involvement of both elders and informal and formal carers that will be involved in the trials.

Accordingly, the components that guarantee the secure handling of privacy related, sensitive data in the system will be designed and developed as an integral part of the tools in WP 3 and WP4.

Keywords: Ethical, Privacy and Legal Considerations

Classification and approval

Classification: Public
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1 Introduction

One of the main objectives of CaMeLi are the system trials in three realistic user environments for validation and assessment of systems functionalities regarding user acceptance and technical viability. As there are human beings involved in these trials, privacy, ethics and data security plays a major role, therefore all evaluation activities insist that ethical and legal principals are strictly followed.

This document acts as a reference book in terms of ethical, legal and privacy issues and therefore covers all ethical criteria that must be considered by all project partners during the whole user requirement engineering and prototype development phase. It is a strategic guide which builds a bridge between the two deliverables D5.2 *Privacy Protection Plan* and D4.1 *Specification of overall system architecture and security and privacy infrastructure*. While D5.2 has it's focus on the user side including Informed consent, user selection, etc. D4.1 has its focus on the implementation of privacy in the related functions of the CaMeLi architecture.

Following the user centered approach of the project an ethical guideline is required to ensure the users' rights in terms of privacy, safety and inviolability. The proper handling of complex questions like e.g. the definition of appropriate data handling procedures underlies the associated work package members who are obliged to satisfy the needs of the involved target users in terms of ethical aspects.

This document therefore only act as a strategic guide that does not constrict the consortium team in its way to apply the ethical demands.

1.1 Relationships with other Deliverables

This Deliverable is strongly related to the Work done for deliverable D5.2: Privacy Protection Plan. Within D5.2 the project will set up an ethics and privacy committee at each pilot site with representatives from each of the trial sites responsible for developing guidelines and codes of practice (documented in deliverable D5.2 Privacy Protection Plan) for use by the project and to also monitor that the guidelines are being properly addressed throughout the project (and beyond it, for issues such as confidentiality of personal data). The ethics and privacy committee will be responsible for all ethical issues related to the involvement of both older persons as well as informal and formal carers that will be involved in the trials.

1.2 Contributors

Table 1: Revision History

Version	Date	Reason	Revised by
V1	24-10-2013	Initial version	M. Dubielzig, M. Lindemann (SAG)
V2	20-01.2014	Updated Version	C. Wings-Kölgen, R. Wintjens, M. Mohrmann (ORBIS)
V3	31.01.2014	Final Version	C. Wings-Kölgen, M. Dubielzig
V4		Reviewed Version	

Table 2: Authors

Partner	Name	Email
SAG	Klaus-Peter Wegge,	wegge@mail.upb.de
	Matthias Lindemann,	matthias.lindemann@xg.upb.de
	Markus Dubielzig	markus.dubielzig@siemens.com
ORBIS	Cindy Wings-Kölgen	c.wings@orbisconcern.nl
	Rachelle Wintjens	r.wintjens@orbisconcern.nl
	Maddy Mohrmann-Meyer	m.mohrmann@orbisconcern.nl

2 Ethical Issues

Ethical issues play a major role when doing research, as they may arise due to competing obligations and conflicts of interest. There are many varieties of ethical issues that may arise whenever human subjects are involved in research. Some of these issues are quite easy to be defined e.g. in medical research, but for social research they are not always clear. Observations, interviews and questionnaires as well as the introduction of new technologies can be intrusive and have negative influence on the participants. Consequently researchers should be bound to a set of basic ethical principles to ensure that no participants are harmed. Universally accepted principles where therefore developed to ensure that the rights, dignity and well being of participants are protected. These principals can be found in the Nurnberg Code of ethical research from 1947 and where updated in the Helsinki declaration in 1975[1]. The following principles were identified as relevant for CaMeLi are the ones that need to be considered during the whole user requirement phase, during implementation and development but will also be followed during the evaluation. A detailed overview of ethical, legal and privacy concerns for the evaluation in the pilot countries can be found in the respective deliverables of WP5. D5.2 also provides the detailed forms like checklists and questionnaires to support the evaluation.

The following chapters and the ethical principles are those that were identified as relevant for CaMeLi and are to be followed during the first requirements specification phase at the beginning of the project:

1. Involved users are provided with information in advance

   Users should get information about the project, the purpose of the evaluation, the risk and the benefit in advance to the evaluation and written in a language and style appropriate to their needs. This information includes a complete disclosure of the test environment, information about the whole nature of the test, what the user is expected to do, etc. Furthermore it should also contain the information, that users may refuse the participation and that they are free to withdraw at any time without giving a reason.

2. Informed consent

   a. Informed consent of involved persons

      All involved users will have to sign an informed consent form (already in use by the user partners) to ensure that their participation is voluntary. Project partners must obtain a signed consent from each user before they can start testing.

      In the case that a user is not able to sign the form, a responsible relative (or carer) may sign the form on his / her behalf. The informed content that will be used in CaMeLi is being developed in WP5 and can be found in deliverable D5.2.

      Signed consent forms are to be kept in a secured place at the responsible project partners. The responsible evaluation manager and the responsible interviewer of the pilot project partners VIVA and ORBIS have exclusively access to the filled consent forms.

   b. Informed consent of involved third parties (care professionals and relatives)

      As CaMeLi will likely interfere the care provided by care professionals and or relatives and friends, it is necessary that they are fully involved and also give a written signed consent if data of them is used in the project.

3. Minimize the risk to the participants

[1] MonAMI D4.1 Criteria for Inclusion Evaluation and Methodology Evaluation

The evaluation/ trial will be designed in a way that the users will not be harmed nor death of disabling injury will occur. The evaluating project partner has to sign a statement which demonstrates all applicable measurements including the existence of insurances of participating staff.

4. Allow participants to end the test at any time

   All participants have the right to stop the evaluation/trial at any time even without the need to explain why and without any fear for undue burdens.

5. Allow the evaluators to end the test if there is risk for the user.

   In case the continuation of the test may cause harm to the users, the evaluator has to stop the evaluation/trail.

6. Respect privacy

   Cultural, religious, gender or other differences in the user group must be handled sensitively and appropriate. Discrimination to and stigmatisation of subjects is strictly forbidden

7. Maintain confidentiality and anonymity

   The evaluator and all persons involved are obliged to not reveal the identity of any user, nor any information which may allow for identification of any user. All results from the evaluation have to be anonymized and stored in a way that the user cannot be identified (if not obtained in an adequate consent) e.g. by:

   a. Using pseudonyms to protect the identity of the users.
   b. Storing all critical data in a locked file or encrypted area on the computer with access only to those researchers that need to have access to them
   c. Using codes for identifying participants
   d. Delete information that could reveal the identity of users carefully

All personal data required to run the CaMeLi-System successfully needs to be protected By applying respective ICT technologies like data encryption, secure networks etc. which will be considered, identified and used in the implementation (See Workpackage 3). Besides these principles the project is following the fundamental legal and ethical framework of the European commission and additionally the national ethical, legal and privacy requirements. Although this will be handled in detail in Deliverable 5.2, the basic framework must be accepted to ensure an objective and value-free user requirement engineering phase in terms of ethical and legal issues. Because this outcome has a direct influence the following WPs. Chapter 3 provides a basic overview of these legal rules.

Because the CaMeLi testing partners have long years experiences in social science and most of their employees are care professionals, they will ensure that these recommendations are already be addressed, during the first user involvement as well as during the development phase and of course during evaluation.

2.1 Testing Environment

In the CaMeLi project there are different potential test sites. The first tests (pre-trials) will be performed in a laboratory environment. Each testing partner has to ensure a testing environment which is safe and comfortable for involved users as well as employees.

The following test phase which also covers the refinement of the prototypes is scheduled to be accomplished in the user's home. As the installation will be in the user's home, the legal and ethical issues that need to be followed are even more complex and will be defined in WP5.

2.2 Selection of users

The consortium includes three different test beds, two at ORBIS and one at VIVA local organizations, authorities and departments who are in charge of older people's affairs. The technical and usability experts of the consortium provide these organisations with the required user of people they wish to participate. For example due to the technical restrictions of the prototype only single households will be taken into account. The local organizations then pre-select a representative set of users complying with the list of criteria for potential users.

The feasibility and usability stage of the CaMeLi testing is small scale and less formal than the later on rolled-out evaluation stage. Therefore, selection for the former follows less precise standards as compared to the latter.

However, in order to optimize the information from the testing, project partners are recommended to seek users who are impartial and who can provide the maximum of feedback on the provided services.

Moreover, in order to obtain sustainable, conclusive results, project partners need to ensure that the selection process of users is fair and unbiased. Deliverable D5.2

All members of the target group who fit the user profile criteria are eligible to participate in testing. Therefore, selection shall not be made on the premise that a user, known by a member of the consortium, will particularly benefit from the services. Similarly, users who may be disfavoured by a member of the consortium cannot be unselected.

The profile criteria are to be general, not describing a particular individual. For instance, a general description can be: Men and woman over the age of 65 years and who experience hearing difficulties when not using a hearing aid.

Disallowed profiling includes any description of a specific individual, for example: "*The male householder who is over 75 years old, living at 22 CaMeLi Road ...*".

All details of the user recruitment process for the pre-trial and final end-user evaluation can be found in the corresponding deliverables of WP5 Pilot Trials and Evaluation.

3 Legislation concerning ethical aspects in research

Besides the general ethical aspects it is very important that also legislation concerning ethical aspects are met in all participating countries. This chapter gives an overview on the legal requirements that are relevant for the whole CaMeLi system development process and the evaluation. Compared to other AAL concepts, CaMeLi will not develop or use new sensors observing the users, neither private nor additional medical data will be collected. However it will use the Kinect to observe the user in their home in an unobtrusive and user accepted way by allowing the user to turn off the device at will. Per se CaMeLi is a standalone system, thus directives for use; processing and storage of personal data can be neglected as no data will leave the users home. However these data shall still be secure and not accessible by any third party that might have direct access to the device. Moreover these directives became important, as soon as the system starts to communicate with external servers, which may be the case when extending the services.

Corresponding directives can be found in the following chapters:

3.1 Europe

- Good scientific practice in research and scholarship European Science Foundation Policy Briefing
- World Medical Association Declaration of Helsinki – Ethical Principles for Medical Research Involving Human Subjects
- Ethical Guidelines developed by Social Research Association (recommended to used by Disability Rights Commission, UK)
- Charter of Fundamental rights of the European Union (2000/C 364/01) (http://www.europarl.europa.eu/charter/pdf/text_en.pdf)
- Directive 2001/20/EC on the implementation of Good Clinical Practice in the conduct of clinical trials on medicinal products for human use (http://www.eortc.be/Services/Doc/clinical-EU-directive-04-April-01.pdf)
- Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data (need of explicit consent by the person on whom data is going to be collected) (http://europa.eu/legislation_summaries/information_society/data_protection/l14012_en.htm)
- Council of Europe, European treaties, ETS no. 108, convention for the protection of individuals with regard to automatic processing of personal data, with amendments and additional protocol (http://conventions.coe.int/Treaty/en/Treaties/Html/108.htm)
- Directive on privacy and electronic communications**.** Directive 2002/58/EC2 (also known as the E-Privacy directive) concerns the processing of personal data and the protection of privacy in the electronic communications sector. It builds on directive 95/46/EC and in particular targets the right to privacy in the electronic communication sector and free movement of data, communication equipment and services.
- Directive on privacy and electronic communications amendment**.** Directive 2006/24/EC (also known as the Data Retention directive) amends directive 2002/58/EC by defining (extra) rules on data retention and the security of data. The directive mandates retention of certain communication data of publicly available electronic communications services or of public communications networks for law enforcement purposes.
- Standard Contractual Clauses for the Transfer of Personal Data to Third Countries Commission Decision 2001/497/EC of 15 June 2001 on standard contractual clauses for the transfer of personal data to third countries under Directive 95/46/EC sets out standard contractual clauses to ensure an adequate level of protection of personal data transferred from the EU to third countries. The Decision requires Member States to recognise that companies or bodies that use these standard clauses in contracts relating to the transfer of personal data to third countries ensure an "adequate level of protection" of the data.

- Standard Contractual Clauses for the Transfer of Personal Data to Third Countries - amendment Commission Decision 2004/915/EC of 27 December 2004 amends Decision 2001/497/EC by the introduction of an alternative set of standard contractual clauses for the transfer of personal data to third countries.

3.2 Germany

In Germany there is no single act implementing ethical rules in research involving humans. According to the multiple facets of modern medical research rules are laid down in different acts on national level and accompanied by regulation by the respective German Federal States. The most important acts are the "Arzneimittelgesetz" (German Pharmaceuticals Act) http://bundesrecht.juris.de/bundesrecht/amg_1976/gesamt.pdf and the "Medizinproduktegesetz" (German Medical Devices Act) http://bundesrecht.juris.de/bundesrecht/mpg/gesamt.pdf. Both require the installation of an ethical committee at each medical research centre and assign the state control for medical research to public authorities. In the field of non-medical trials with elderly or disabled people there is no clear regulation yet. But the "Allgemeines Gleichbehandlungsgesetz" (Equal Treatment Act) http://www.gesetze-im-internet.de/bundesrecht/agg/gesamt.pdf enacted in 2006 and the "Behindertengleichstellungsgesetz" (German Equal Rights of Persons with Disabilities Act) http://www.gesetze-im-internet.de/bgg/index.html provide reasonable guidance.

Legislation concerning data protection
The German Act on data protection as well as the respective Acts of the German federal states aims to protect the individual's right to the protection and confidentiality of their personal data.

For Siemens as a leading IT company, data protection is more than crucial. Siemens is committed to follow the companies' strong rules world wide. These rules are publish at http://www.siemens.com/corp/en/index/privacy.htm or can be downloaded at http://www.siemens.com/corp/en/index/privacy.htm

3.3 The Netherlands

The following legislation and regulations concerning ethics in science, apply in the Netherlands:

- The Medical Research Involving Human Subjects Act (Wet medisch-wetenschappelijk onderzoek met mensen (WMO)) http://wetten.overheid.nl/BWBR0009408/geldigheidsdatum_24-01-2014
- 'The Netherlands Code of Conduct for Scientific Practice', from the Association of Universities in the Netherlands. http://www.vsnu.nl/files/documenten/Domeinen/Onderzoek/The_Netherlands_Code_of_Conduct_for_Scientific_Practice_2012.pdf

Above mentioned act and code are both based on the Helsinki Declaration drafted by de World Medical Association. Although these legislation and regulations are not fully applicable to CaMeLi, as it is not medical research or research in which the participants are subjected to specific behaviour, the principles of the WMO and the Code can be applied.

The most important principles are:

1. Scrupulousness
2. Reliability
3. Verifiability
4. Impartiality
5. Independence

Derived from these principles the most important applicable points are first and foremost the interest and well-being of the participants, their voluntary participation and the possibility to withdraw from CaMeLi at any time.

Legislation concerning data protection

The Dutch "Law Protection of Personal Details" (http://wetten.overheid.nl/BWBR0011468/geldigheidsdatum_24-01-2014), which is the Dutch implementation of the European Directive 95/46/EC, defines rules and procedures how organisations have to deal with personal details. The Dutch institute College Bescherming Persoonsgegevens (CBP) is the data protection agency that sees to it that rules are obeyed by organisations and companies. The law defines who is allowed to have access to which data and for which purpose in line with the principles set by the directive: transparency, legitimate purpose and proportionality. Also people are offered certain rights over data held about them such as the right to know what is held about him and the right to have errors corrected.

Applied to CaMeLi this means that collection and processing of data must meet the conditions defined by law and that the elderly or assisted person in CaMeLi, or his/her legal representative, can exercise some level of control over the information.

The target group of CaMeLi consists of "big group of healthy elderly or with light physical or mental health problems", which may expand the scope of CaMeLi towards healthcare. In such case the "Wet Geneeskundige Behandelingsovereenkomst '' (Law Medical Treatment Agreement) http://wetten.overheid.nl/BWBR0007021/geldigheidsdatum_24-01-2014 may apply, which mandates that patients be properly informed regarding their treatment, mandates dossier keeping and patient related rights. For privacy the "Wet Bescherming Persoonsgegevens" remains applicable. A special case may be in case of emergency, which allows for exceptions to the general privacy rules.

3.4 Swiss

In Switzerland the data protection law is mainly governed by the Federal Act on Data Protection (DSG) of 1992. In addition, further data protection statutes are also found at individual canton levels which are relevant to CaMeLi. In the Canton of Geneva the related law is the « *Loi sur l'information du public, l'accès aux documents et la protection des données personnelles LIPAD RS A 2 08* ». According to art. 3.2 of LIPAD this law is applicable to all public and public law institutions (« *a) les pouvoirs exécutif, législatif et judiciaire cantonaux, ainsi que leurs administrations et les commissions qui en dépendent; b) les communes, ainsi que leurs administrations et les commissions qui en dépendent; c) les établissements et corporations de droit public cantonaux et communaux, ainsi que leurs administrations et les commissions qui en dépendent; d) les groupements formés d'institutions visées aux lettres a à c* ».

Therefore the LIPAD is directly applicable for both the University of Geneva and VIVA. As the Cantonal law is similar to the federal law (the federal law directly influences the canton law's interpretations) both sources will be mentioned. However, the legally binding provisions are those of the LIPAD for the Geneva Canton.

According to art 12 DSG (art. 35 LIPAD), the institutions and persons holding and processing personal data must can disclose sensitive personal data or personality profiles to third parties only when a loi specifies clearly the work that needs to be accomplished or if the concerned person has given his consent (LIPAD 35.2 "*avec le consentement explicite, libre et éclairé de la personne concernée*").

In addition (LIPAD art 35.1) the processing of data can be legitimate if the processing is necessary for the fulfilment of their legal tasks. This part clearly covers the requirements and needs for the CaMeLi project.

The collection of personal data is authorized by LIPAD (art. 38.1) as long as the collection is done in a way that is clearly recognizable by the concerned person.

The transfer of personal data to other entities or persons is governed by LIPAD art. 39, where all cases and rules under which the data transfer can take place are described. LIPAD defines different rules for the transmission of personal data, depending on the receiving entity. It distinguishes the following entities that can receive personal data and defines the rules that govern the transfer:

a) Another public institutions that is falls under the data protection law

b) A Swiss corporation or public law entity that is not under the data protection law

c) A foreign corporation or foreign public law entity

d) A third person or entity which is under private law

LIPAD also defines how the personal data can be used after the completion of the task for which they had been collected (art 41). For that LIPAD defines that the data are either destroyed or anonymized for the purposes of research, planning and statistics. In addition the publication of the must be done in such a manner that the data subjects may not be identified.

According to LIPAD (art 44) any person can has the right to ask the responsible entities holding their personal data to be informed by whom their information is handled (art 44.1), ask that their information is destroyed, corrected or restrict access to others (art 47.1).

Territorial Application

The application of EU Data Protection Directive is limited to the territory of the EU states and of the EEA states, (Norway, Iceland and Lichtenstein).In general, each state is applying its national law adopted based on the DP Directive.

Switzerland, not being a member of the EU, applies its own federal law which is outside of the scope of DP Directive. However, the Swiss law follows the same approach as the DP Directive and the law was also recognized as providing adequate data protection for the purposes of transfer of personal data outside of EU/EEA. The European Commission has taken a Decision pursuant to Directive 95/46/EC stating that the level of Data protection is equivalent to that in the EU. That has as a consequence that personal data may be transferred to Switzerland just as if Switzerland was member of the European Union. No additional issues arise therefore from the fact that one of the partners is based in Switzerland.

4 Privacy and security

Based on legal requirements, all information about participants gathered during the evaluation is confidential unless otherwise agreed in advance. Participating users have the right to expect that their information is treated confidentially and if published the information will both be identifiable as theirs. In case this cannot be guaranteed, the users shall be informed about this prior to their agreement.

In the CaMeLi project handling and storage of personal information shall be realized confidential and all personal information is exclusively used for research. To ensure this, data will be made anonymous by replacing the names by unique numbers and will be stored in a separate secure place. The numbers do not give any indications on the persons identity.

To ensure a reliable service and infrastructure the following requirements must be supported. Details about the used algorithms and encryption can be found in D4.1 Specification of overall system architecture and security and privacy infrastructure.

Security and privacy directives

The default CaMeLi prototype will be available as a standalone system which does not require any internet connection. Later on, this device can be extended with different server sided service modules which may also require internet connection. Nevertheless, the following privacy and security definitions are related to the standalone device and should therefore be adapted before delivering a client/server solution to the end users.

Access authorization

The CaMeLi prototype is a personal, user related device and therefore supports an appropriate authentication mechanism that only allows registered users to control the device itself as well as to configure and install existing or new services on the device. Nevertheless, for training or additional administrative purposes, a kind of supervision routine is provided to reset the device in case of hardware or similar problems. System authentication routines and user level based access control (e.g. authorized file manipulations) should be monitored and locally stored for recovery and integrity reasons.

Data privacy and integrity

All available user data on the device is by default encrypted and manipulation of stored data requires a (local) system login of a registered user who has the appropriate access rights to open, edit and safe data. Each data transfer is accomplished by following a suitable transmission method which provides reliable and secure communication handling to assure the highest level of data privacy. All performed backups of the user data that are stored on other devices (like e.g. usb keys) also underlie the above mentioned restrictions.

Illegal access protection

Illegal data manipulation by unauthorized (and therefore non-registered) persons will be detected by the CaMeLi system to prevent forbidden data transmissions. Backup strategies must also consider the above mentioned access control aspects.

Intrusion detection and system integrity

The CaMeLi system should provide intrusion detection mechanisms (like e.g. auto log file analysis routines) to prevent (as well to reveal) local as well as external system attacks. Low and high level file system access should continuously be monitored to create a complete system history which moreover provides an appropriate basis for system recovery. Ingenious software refuelling, configuration and administration routines should prevent the system against virus infection or similar malware attacks. Service databases should be well-defined and database installation routines should check against the consistency of the required DBMS structure. In case of a client/server configuration of the CaMeLi system, a honey pot strategy could be realized to discover the potential sources of external system attacks.

5 Glossary

Table 3: List of terms, abbreviations and acronyms

AAL	Ambient Assisted Living
ICT	Information and Communication Technology

Annex A: Check List

The following checklist shall be used before any users are interviewed. It is intended for the interviewer to ensure that all issues have been solved before the evaluation starts.

Participants	
Have all participants signed the informed consent? (Copies must be kept at the pilot organization)	☐
Have all participants been informed before the evaluation?	☐
Documentation of the participants recruiting and selection process	☐
Personnel	
Is there a list of all personnel involved in the evaluation	☐
Are all personnel aware of the ethical issues related to the evaluation?	☐
Data protection	
All relevant International, European and national legislation have been addressed.	☐
Does each user have a non-identifiable ID number?	☐
Is personal data kept in a secure place?	☐
Legal/Ethical	
All relevant International, European and national legislation have been addressed	☐
Methodology	
Documentation of methodology used in testing	☐
Templates used to collect data	☐
Documentation of guidance for testing	☐
Insurance	
Documentation of insurance coverage	
Documentation of indemnity coverage	

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