

Report on ethical issues

Author(s): Cornelia Schneider, Birgit Trukeschitz, Ralph Eichenberger, Susanne Ring-Dimitriou

Organisation(s): Salzburg Research Forschungsgesellschaft mbH
Vienna University of Economics and Business
Eichenberger Szenografie
Paris Lodron Universität Salzburg

Document Number: D9
Version/Date: 0.7/02.11.2016
Document Type: Deliverable
Dissemination Level: Public
Checked and released by: Viktoria Willner

Funded by the European Commission and Partner States within the Active and Assisted Living Programme

Revisions

Rev.	Date	Author	Description
0.1	5.9.2016	Cornelia Schneider	Document structure
0.2	6.9.2016	Cornelia Schneider	Incorporation of feedback from Harald Rieser
0.3	7.9.2016	Cornelia Schneider	Incorporation of feedback from Verena Venek
0.4	31.10.2016	Cornelia Schneider	Incorporation of feedback and input from Tanja Kefer regarding care guidelines
0.4	31 Oct. 2016	Birgit Trukeschitz	Comments to the draft
0.5	31 Oct. 2016	Susanne Ring-Dimitriou	Comments and Amendments
0.6	01 Nov. 2016	Ralph Eichenberger	Input for 5.2.1 and 5.2.2
0.7	02 Nov. 2016	Viktoria Willner	Final review

Acknowledgement

We thank Viktoria Willner (Salzburg Research) for her valuable input and feedback in course of the review of this deliverable. Any errors remain the responsibility of the authors.

Table of Contents

Revisions.....	i
Acknowledgement.....	i
List of Tables.....	iii
1 Introduction	1
1.1 Purpose of the document	1
1.2 Definitions, acronyms and abbreviations	1
1.3 Relationship to other deliverables.....	1
1.4 Structure of the document	1
2 Why ethical considerations?.....	1
3 Lead Users.....	2
3.1 Obligations	2
3.2 Information policy	2
3.3 Rights to exit	2
4 Trial participants.....	2
4.1 Obligations of trial participants	3
4.2 Information policy	3
4.3 Rights to exit and rewarding their participation	3
5 Ethical issues within different project phases.....	4
5.1 Understanding - User requirements.....	4
5.2 Conceptualising - Design/Implementation & Integration	4
5.3 Testing & Evaluating	5
6 Care guidelines ethical and legal issues.....	6
7 References.....	8



List of Tables

Table 1: Care Guidelines and Competencies	7
---	---

1 Introduction

1.1 Purpose of the document

This document represents the official deliverable D9 of the AAL JP project CiM – CareInMovement. Especially for projects where human beings are involved as lead users and field trial participants’ ethical and legal issues have to be considered. In this document, ethical and legal issues concerning end users in different project phases are described. Additionally, ethical aspects regarding care guidelines developed within the project are addressed.

1.2 Definitions, acronyms and abbreviations

AAL	Ambient Assisted Living/Active and Assisted Living
Primary end users	Care service users (retired people 55+ with limitations in mobility)
Secondary end users	Informal carers (family members and volunteers) and formal carers
DoW	Description of Work
Lead user	Consumers with needs representative for the market
CiM	CareInMovement the project
CARIMO	ICT system developed within the project CareInMovement

1.3 Relationship to other deliverables

This deliverable relates to task 2.6 ‘Ethical issues and legal issues’ of the DoW. Furthermore it relates to D4.1 User Requirements and D12 Security Concept.

1.4 Structure of the document

This document starts off with a short reflection on the need for ethical considerations (chapter 2). Then lead users, their rights and obligations are described (chapter 3). Chapter 4 deals with trial participants their rights and obligations. Ethical issues within different project phases are described in Chapter 5. Chapter 6 addresses ethical issues related to the care guidelines we develop for the project.

2 Why ethical considerations?

To ensure user acceptance of the CiM system (CARIMO), end users (care recipients, family carers, volunteers and social care organisations) will be involved in all project phases. As in many AAL-projects, our primary target group cannot be regarded as “ICT literate” or ‘digital natives’, we have to develop rules and processes related to ethical and legal issues and information strategies in dealing with our lead users (pre-intervention phase) and end users (intervention / field trial). Additionally, ethical and legal aspects have to be considered in the system design.

As the CiM-consortium takes ethical issues seriously, we applied for a vote of the ethical committee of the Paris-Lodron-University Salzburg. The study proposal was positively reviewed and we got the vote for it on 2 November 2016.

By clearly defining rights and obligations of lead users and trial participants as well as rules and processes on how to deal with end users (in different project phases), clarity and transparency regarding ethical and legal issues will be provided for all project partners and users involved in the project.

Additionally, ethical and legal issues regarding care guidelines and users addressed (family members, volunteers and home help) will be described.

3 Lead Users

In CiM lead users are members of the target group of CARIMO in Austria and Italy. Their task is to participate in various activities for developing and tailoring CARIMO in the pre-intervention phase. Accordingly, the lead users support the project team in developing a user-centred and user-friendly ICT-solution to increase safety and mobility of end-users in their dwelling place.

Ideally, the lead user pool should remain stable during the project, especially in the pre-intervention phase. For each country at least six primary end users, three family members, three care professionals and three potential volunteers have to be recruited. Lead users will be recruited by the end user organisations in each country.

3.1 Obligations

Lead users do not have any obligations. They take part in workshops with CiM project members to support/consult the project team in developing the AAL-solution on a voluntary basis.

3.2 Information policy

Lead users are recruited by the end user organisations. They get some information about the project (2 pages flyer) when they are recruited.

If a lead user is interested in participating in workshops he/she will be informed in detail before a workshop by the end user organisation.

3.3 Rights to exit

Each lead user recruited by an end user organisation has the right to terminate his/her commitment to act as lead user at any time. This can be done without giving a reason. Each lead user will be informed about the project and the project progress by the respective end user organisation.

4 Trial participants

CARIMO will be tested for 8 months within two care regimes, one in Austria and one in Italy. In each country 60 primary end users (long-term care service users), 60 family members, 40 volunteers and 9 formal carers will be involved in the trial. Additionally, a control group of 60 primary end users (long-term care service users) in each country will be established.

4.1 Obligations of trial participants

If people decide to participate in the field trials, they will sign an informed consent and agree to participate in the project on a voluntary basis. Their task will be to test CARIMO for 8 months. Additionally, they agree to participate in assessments regarding the usability and the efficacy of the system (questionnaires, interview, and functional fitness tests).

4.2 Information policy

During the recruitment process potential field trial participants will be informed by employees of the end user organisations about the project and about the field trial. Tailored information material will be distributed for this purpose.

If an end user is interested in participating in the field trial, he/she will be informed in detail about the field trial by an employee of the respective end user organisation and an informed consent will be handed out. Then, the potential field trial participant has 14 days to decide whether he/she wants to take part at the study by signing the informed consent or not.

4.3 Rights to exit and rewarding their participation

Each trial participant has the right to terminate his/her commitment to participate in the field trial at any time (before the start of the field trial and during the field trial). This can be done without declaring a particular reason. However, for evaluation purposes trial participants who dropped out will be asked to report their reason(s).

In the Description of Work (DoW) we proposed two possibilities to exit the project:

1. **Dissatisfied** end users: Devices will be collected and user data will be deleted. They are asked to fill in a final questionnaire for feedback (in order to learn why they are dissatisfied).
2. **Satisfied** end users: They will be granted the right to keep the system for free until market launch. After market launch they will have the possibility to use the system on favourable conditions.

After some discussions in the consortium we decided that we cannot promise that the test system will be available on the market. The system ready for the market will need improvements and adaptations according to the plans of the business partners. Therefore, we have revised our exit strategy as follows:

Strategy for **primary end users**:

1. **Quit during field trial**: Devices (tablet and wearable) will be collected; if field trial is terminated before trial end (in written or oral form) data will be deleted if desired. They will be asked to give a short feedback to their end user organisation (in order to learn why they dropped out).
2. **Completed field trial**: If they finished the field trial and used the system regularly (at least 3 times a week) they will be granted to keep the wearable. This device will then be configured to work autonomously without the CiM-system. Additionally, if CARIMO will be launched on the market (maybe with some adaptations – less functions or new functions – depending on the evaluation results), they will have the possibility to use the system on favourable conditions.

Strategy for secondary end users, i.e. **volunteers and family members**:

1. If the trial is terminated before trial end (in written or oral form) data will be deleted if desired. They will be asked to fill in a final questionnaire for feedback regarding the drop out.
2. For secondary end users who finish the trial gratification will be made by organizing a jointly breakfast in their region.

5 Ethical issues within different project phases

In the CiM project, users are directly involved in the project phases “Understanding”, “Conceptualising”, and “Testing” & “Evaluating” (according to Nedopil, Schaubert, and Glende 2013). Additionally, they are indirectly (via field trial results) involved in business modelling. The following sections describe information strategies, processes and rules for user involvement in each project phase.

5.1 Understanding - User requirements

User requirements have been collected in two lead user workshops in Italy and Austria.

Information strategy:

- Potential lead users will be informed about the workshop by employees of the end user organisation
- If interested, they get a written invitation for the workshop and additional information about the project

Rules:

- Oral invitation
- Written invitation
- Information about project and project progress
- Informed consent for tape recording if needed
- Workshop aims
- Announcement of further appointments

Process:

- Potential lead users will be informed about the workshop by employees of the end user organisation
- Written invitations will be delivered 2 weeks before the next workshop appointment by the end user organisation
- Lead users will be reminded personally by the end user organisation 2 days before the workshop; if needed, the transport to the workshop is organized
- Workshop
 - People are informed about the project (progress)
 - People are informed about the aims of the workshop
 - People are informed about further appointments

5.2 Conceptualising - Design/Implementation & Integration

The design will be tested in two acceptance tests with lead users, as described above, in Austria and Italy. Both tests will cover the following three parts:

- Interface design
Testing readability, font size, colours, contrast, imaging, wording and the size of the interaction elements (buttons)
- Interaction design
Testing usability; the lead users will have to carry out different tasks (e.g. finding a specific newsletter article and returning to the start screen, adding a performed task to the task list and returning to the start screen)
- Product design
Testing the value proposition of the system as a product and the usefulness of each functionality

The first test focuses on the tablet app using paper mock ups for all screens. In the second test the tablet app and the web app will be tested. As agreed in the consortium, the complete tests will take place in Austria only. In Italy the interface design will be tested with a group of lead users.

The second test will be conducted with a running system on tablet and desktop computers. Care recipients will test the interface design and the interaction design of the tablet app. Volunteers, informal caregivers and formal caregivers will test the interface design and the interaction design of the tablet app and the web app

5.3 Testing & Evaluating

The project phase “testing & evaluation” comprises the field trial and all measures taken to evaluate the usability and effectiveness of the CiM-system during the field trial. Ethical issues relate to the trial design, information policies and the instruments used for evaluation.

Trial design:

The trial design has been approved by the ethical committee of the Paris-Lodron University Salzburg. ALDIA will clarify whether they will need a vote or not

Primary and secondary end users are only allowed to participate if they have read, understood the project aims and procedures and signed an informed consent form. The informed consent will be drafted by Salzburg Research, WU, PLUS and Hilfswerk and then translated into Italian.

In addition to ethical approval, Austrian partners will register the CiM project to the data protection authority

Information policies:

- Primary end users and their relatives will be recruited and informed by employees of the Hilfswerk and ALDIA New volunteers will be recruited during events of ALDIA and Hilfswerk
- Both organisations plan to include existing volunteers of their organisations
- Formal carers of both end-user organisations will be introduced in completing three functional tests)
- All end users will be provided with a phone number of the responsible end user organisation.

Rules:

- Informed Consent for each country (Austria, Italy)
- Clarification if a vote of an ethics committee is needed (Austria, Italy)
- Clarification if additional ethical or legal steps are necessary (Austria, Italy)
- Identical contents of training course for testing functional fitness (Austria, Italy)

Process:

- The informed consent will be translated into Italian
- Ethics committee Austria
 - SFRG, WU and PLUS will submit a proposal to the ethics committee of University of Salzburg
- Ethics committee Italy
 - ALDIA will clarify if they need a vote from an ethics commission or not
- Testing procedures of functional fitness (handgrip, 30s-stair rise test) will be introduced personally and by an online education course for formal carers.

6 Care guidelines ethical and legal issues

The care guidelines have been developed with respect to Austrian law

(<https://www.ris.bka.gv.at/GeltendeFassung.wxe?Abfrage=Bundesnormen&Gesetzesnummer=10011026>,

<https://www.ris.bka.gv.at/GeltendeFassung.wxe?Abfrage=LrSbg&Gesetzesnummer=20000616>). For Italy the guidelines have been checked by ALDIA.

For each care guideline it is designated who is allowed to carry out the activities.

Care Guideline	Home Care	Home Help	Relatives	Volunteers
Support for getting dressed	x		x	x
Support for getting undressed	x		x	x
Support with walking aids	x	x	x	X
Support for walking	x	x	x	x
Support for showering	x		x	x
Motivate to perform exercises	x	x	x	x
Support for washing at the wash basin	x	x	x	x
Eating support	x		x	x

Toilet training support	x		x	x
Transfer assistance	x		x	x
Perform motion exercises	x		x	x
Agility support	x		x	x

Table 1: Care Guidelines and Competencies

7 References

Nedopil, Christoph, Cornelia Schaubert, and Sebastian Glende. 2013. "Guideline the Art and Joy of User Integration in AAL Projects. White Paper for the Integration of Users in AAL Projects, from Idea Creation to Product Testing and Business Model Development." Brussels.