Project Identification	
Project Number	AAL-2011-4-112
Duration	36 months
Coordinator	Andreas Rumsch
Coordinator Organization	Hochschule Luzern – Technik & Architektur, iHomeLab (IHL)
Website	www.iwalkactive.com

Ethical Manual

Document Identification	
Deliverable ID	D1.1 Ethical Manual
Release number/date	V5.0 2013-02-22
Checked and released by	Stefan Kindberg

Key Information from "Description of Work"	
Deliverable Description	This project manual builds the basis for the project partners on how to follow ethical rules and guidelines
Level	PU = Public
Deliverable Type	R = Report
Original due date	2012-11-15

Authorship & Information	
Editor	Stefan Kindberg, TRI
Partners contributing	AIT, IHL, TRI
Reviewed by	Andreas Rumsch IHL, Martin Biallas IHL

Release History

Release Number	*Date*	*Author(s)*	*Release description /changes made*
V 1.0	2012-09-04	Martin Morandell, AIT	Previous document partly adapted to iWA
V 2.0	2012-12-12	Stefan Kindberg, TRI	Partly complete draft incl. appendices
V 3.0	2012-12-16	Stefan Kindberg, TRI	Partly complete draft incl. appendices
V 4.0	2013-01-15	Stefan Kindberg, TRI	Complete draft incl. appendices
V 5.0	2013-02-22	Stefan Kindberg, TRI	Final version reviewed and approved by IHL

iWalkActive Partners

iWalkActive (AAL-2011-4-112) is a project within the AAL Joint Programme Call 4.

The consortium members are:

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Table of Contents

Abbreviations

Abbrev.	*Description*
AAL	Ambient Assisted Living
AAL JP	Ambient Assisted Living Joint Programme
iWalkActive	Acronym of this Project – iWalkActive – an Active Walker for Active People

1 Introduction

1.1 Background

This ethical manual is intended for the research and development project iWalkActive. The project is financed by the European Union (EU), through the AAL Joint Program, and by national authorities in the respective countries represented in the consortium (National Contact Points).

The goal of the iWalkActive project is to develop a new walking aid with a range of additional applications and services that together will increase individual mobility among elderly people in an enjoyable and motivating way.

Extensive end user involvement will be a vital part of the project, in order to guarantee that the new products and services are of relevance for the intended target group. Relevant literature suggests that end user involvement has generally positive effects, especially on user satisfaction, and involving end users as a primary source of information is an effective means of capturing user requirements when developing new products and services.

This ethical manual stipulates, based on national law and the guidelines of the EU, the code of conduct for the researchers, developers and administrative persons involved in the project. The manual refers to main regulations as regards data security in order to ensure that all project partners uphold maximum data security during and after the project.

1.2 Purpose of the Ethical Manual

This ethical manual stipulates the code of conduct for the researchers, developers and administrative persons involved in the iWalkActive project. The manual refers to main regulations that apply in the European Union and the respective states/countries of the participating project partners, as regards the protection of personal data security, in order to ensure that all project partners uphold maximum security during and after the project.

It is a binding document that contains ethical guidelines and principles, and the ethical manual builds the framework for the self-regulation of all personnel working within the iWalkActive Project.

It also serves the purpose to uphold the trust between all persons collaborating within the project, such as researchers, developers, end users, etc.

1.3 Definitions

1.3.1 Test phase

A “test phase” is a defined period of time where developed products and services will be tested in practice. For the tests, statistical and analytical methods will be used in order to gather information and knowledge about the applicability and suitability of the products and services tested.

The outcome of the test phase will be made public only in such a way that it does not interfere with the consent given by the participants in the test.

1.3.2 Test leader

The test leader is an organisation, represented by an appointed person, that is responsible for the organisation and execution of the tests. This role can vary from test to test, but has to be assigned to a specific organisation and person in advance.

1.3.3 Interviewee

An interviewee is any person or organisation, from whom data and information is collected in a structured way, other than by practically testing devices or services.

1.3.4 Interview

An interview is defined as any form of contact with an interviewee in order to collect information and data to reach a certain goal.

1.3.5 Test Subject

A test subject is any person involved in practical trials of products and/or services, in order to collect feedback and user experiences as regards the tested device and/or service.

1.3.6 Test

A test is the attempt to try out developed products and services in a practical way, in order to gather information about the applicability, usability and operability.

2 Project Description

The goal of the iWalkActive project is to develop a new walking aid with a range of additional applications and services, that together increase peoples' individual mobility in an enjoyable and motivating way. The new products and services shall offer tailored outdoor/indoor navigation and orientation services, as well as motor-assisted support for walking.

Target group: Active people 60-85 years old, with different levels of mobility and activity.

The main goal of the project is to improve the quality of life among elderly people.

2.1 User-centered design - UCD

User-centered design (UCD) is an approach to design that grounds the process in information about the people who will use the product or service. UCD processes focus on users through the planning, design and development of a product or service (Ref.1: Usability Professionals' Association).

There is an international standard that is the basis for many UCD methodologies. This standard (ISO 13407: Human-centred design process) defines a general process for including human-centered activities throughout a development life-cycle, but it does not specify exact methods.

Once the need to use a human-centered design process has been identified, four activities form the main cycle of work:

1. **Specify the context of use:**
   Identify the people who will use the product or service, what they will use it for, and under what conditions they will use it.
2. **Specify requirements:**
   Identify the user goals and business requirements that must be met for the product / service to be successful.
3. **Create design solutions:**
   This part of the process may be done in stages, building from a rough concept to a complete design.
4. **Evaluate designs:**
   The most important part of this process is that evaluation – ideally performed through usability testing with actual users – is as integral as quality testing is to good software development.

The USD process ends – and the product / service can be released – once the requirements are met.

Based on the methodology of User-Centered Design, the iWalkActive project will be executed according to the following steps/work packages (WP):

1. Requirements / Analysis Phase (WP2)
2. Design Phase (WP3-5)
3. System Integration & Test (WP6)
4. Pilot / Field Trials (WP7)

2.1.1 Requirements

The main objective of this phase is to understand the needs and wishes of the target groups addressed by the project, in order to guarantee that the outcome of the project will benefit the end users.

End-user requirements will be gathered through general surveys, focus groups, questionnaires and interviews.

In addition, the requirements of the project's business and research partners, as well as other stakeholders, must be established, with the aim of securing a successful dissemination and exploitation of the result of the project.

2.1.2 Design

The design phase will consist of three blocks:

1. **Applications & Services (WP3)**
   The establishment of a basic software infrastructure, onto which a range of ICT-based applications and services will be developed.
2. **Indoor & Outdoor Navigation (WP4)**
   The objective is to develop indoor and outdoor navigation services, that are tailored for the target group with the aim to support their chosen activities.
3. **Walker Improvement (WP5)**
   The development of an electric drive, to be implemented with the walker, as well as additional improvements with the aim to improve the mobility of the end user.

2.1.3 System Integration & Test

The main purpose of this phase is to integrate all components developed into a running system. All prototypes will be tested and validated, in order to guarantee the safety of the test subjects in the following field trials.

2.1.4 Pilot / Field Trials

The objective of the field trials is to get the products, applications and services developed within the project tested by actual end users, with the aim of evaluating their functionality, usability and user benefits.

Through the evaluation of the test results and the feedback/input from the test subjects, the prototypes will be cause for necessary improvements.

The main purpose of the field trials is to ensure that the outcome of the project benefits the end user also in reality.

3 Ethical Principles & Guidelines

3.1.1 Fundamental Principles

The following fundamental principles apply to all iWalkActive project partners for the full duration of the project;

- Persons working for the iWalkActive project must perform all their work strictly following the principles, guidelines and national regulations as stated in this document.
- Persons working for the iWalkActive project must behave ethically correct and in such a way that they do not harm the project, any of its partners or the field of research in general.
- All persons participating in interviews and tests do this based on their own choice. Therefor all project members must treat these persons in a respectful way.
- The rights of the test subjects must be granted at all times by all persons working on the project. No actions should be taken that might harm or wrong-do the test subjects, neither direct nor as a consequence of their participation in a test or interview.
- Data protection has to be guaranteed throughout the project. Personal data must never be used or revealed outside of the project.
- Project members have to conduct and document their work in an exact, transparent and objective way.

3.1.2 Ethical Principles

The four principles of biomedical ethics, as composed by Beauchamp and Childress (Ref.2: Beauchamp et al 2008), have been chosen as the basic ethical principles for the iWalkActive project.

Beauchamp and Childress' principles for research are some of the most widely used frameworks and they offer a broad consideration of medical ethics issues in general, not just for the use in a clinical setting.

The four principles are general guides that leave considerable room for judgement in specific cases.

The four principles are:

Respect for autonomy: respecting the decision-making capacities of autonomous persons; enabling individuals to make reasoned informed choices.

iWalkActive: the project partners will fully respect all test subjects' decisions about participation / non participation in the project. The project will provide potential test subjects with information in an appropriate way, including information about risks and possibly arising problems.

Beneficence: this considers the balancing of benefits against risks and costs; with the aim to benefit the test subjects.

iWalkActive: the project partners will only perform user tests at the stage where prototypes are considered as safe, while at the same time offering the test subjects as many benefits as possible.

Non maleficence: avoiding the causation of harm; the research trials should not harm the participating person. Research trials might involve some minor harm, but the harm should not be disproportionate to the benefits of the trials.

iWalkActive: although the participation in field trials will demand a certain effort from the test subjects, the project partners should keep these efforts as minimal as possible.

Furthermore, the iWalkActive project partners will try to make the user involvement as interesting and pleasurable as possible for the test subjects.

All prototypes that will be tested by the test subjects during the field trials (WP7) will initially undergo pilot trials in order to avoid any malfunctions and/or failures that could cause the test subjects physical harm.

Justice: distributing benefits, risks and costs fairly; the notion that participants in similar positions should be treated in a similar manner.

iWalkActive: the project partners aim to make as much of the gained knowledge as possible available to the public.

The aim of the project's business model will be to bring the results of the project to as wide a market as possible, in order to offer benefits to all stakeholders, but in particular to realize products and services that will offer benefits to elderly people.

3.1.3 General Guidelines

The project, especially the field trials, must be executed in a legal, candid, honest and objective way, and it must also be organized and executed following academic principles.

The rights of the test subjects have to be considered at all times. The project partners must not be allowed to carry through anything that could harm the test subjects while they are taking part in the project and the associated field trials.

The execution of the project has to be carried through in a responsible way, and common ethical business rules must apply at all times.

The test phase has to be separated from non-research activities in a clear way, in particular all activities that are connected to exploitation and commercialisation.

3.1.4 Integrity

The test subject's confidence in the iWalkActive Project and its partners must not be affected, neither by the organization, the execution nor the interpretation of the tests and interviews. In particular, any assumptions as regards the ability, experience and activity among the target group that might lead to a negative view of the target group, must be avoided. Test situations, interviews, etc. have to be organized in such a way that they do not risk to collect negative data from the test subjects as a result of their limited experience and/or knowledge in/from the research domain.

3.1.5 Voluntary participation

All test subjects and interviewees will participate in the iWalkActive project on a fully voluntary basis, and they must not be misled in any situation.

A person's decision to partake as a test subject or interviewee is not binding, and he/she can prematurely end the participation at any chosen time.

3.1.6 Safety

All project partners and persons involved in the iWalkActive project must at all times take appropriate measures in order to ensure that the voluntary participants are not subject to apparent danger, physical harm or any wrong-doing as a result of their participation in the test and/or interview.

3.1.7 Transparency

The test situation and the scope of the research have to be explained at the beginning of each test/interview situation.

It must be simple for the test subject / interviewee to receive accurate information about the background, content and aim of the project.

If required, the test subjects / interviewees should be allowed to control the quality of the field trials through an external source (at their own cost). As far as required, any technical details have to be provided to the test subjects, without endangering any immaterial property rights.

The test leaders have to ensure that the test user involvement is organized, executed and documented in an exact, transparent and objective way.

3.1.8 Monitoring

Before the interview or test starts, the interviewees and test subjects must be informed about the type of monitoring and recording instruments that will be applied, except when the interview or test is carried out in a public area with no personal data being collected. The data and relevant part of any recordings have to be deleted / destroyed if the test subject so requests. If there is no special agreement about the contrary, the identity of the test subject must be protected at all times.

4 Participation & Informed Consent

4.1 Introduction

The iWalkActive consortium guarantees that no participants, interviewees or test subjects will take part in the project without having signed an Informed Consent. The Informed Consent should include relevant project information that describes what an eventual participation will involve, and also a consent form to be signed by the participant who decides to take part.

Potential participants, interviewees and test subjects should in understandable terms be informed about potential benefits, risks, inconvenience or obligations associated with the project that might reasonably be expected to influence their willingness to participate.

After having been informed about the project, the potential participant must be given sufficient time in order to consider the decision to take part or not.

Where participants are involved in longer-term data collection, the use of procedures for the renewal of the consent at an appropriate interval should be considered.

No inducement to participate should be offered prior to seeking consent, either in the form of payments or of gifts. Reasonable recompense for inconvenience and time contributed to the research, and reimbursement of travelling expenses, can be offered.

4.2 The Right to Withdraw

Any participation as an interviewee and/or test subject is fully voluntary. Participants should be informed clearly that they at any time have the right to withdraw their consent, and withdraw from their participation, and that any data that they have provided will be destroyed if they so request and that there will be no resultant adverse consequences.

4.3 Informed Consent Document

Please see Appendix A.

5 Anonymity, Confidentiality & Data Protection

People participating in research have the right not to have their identities or personal data revealed. Data protection implies informing the participants about who has access to their data and what may be done with this data. It also implies that the project partners handle the collected data with great care and according to relevant laws and regulations.

Except where explicit written consent is given, researchers and project partners should respect and preserve the confidentiality* of participants' identities and data at all times. The procedures by which this is to be achieved should be specified in the project protocol.

*Note that the duty of confidentiality is not absolute in law and may in exceptional circumstances be overridden by more compelling duties such as the duty to protect individuals from harm. Where a significant risk of such issues arising is identified in the risk assessment, specific procedures to be followed should be specified in the protocol.

All data and information collected within the iWalkActive project must be handled in accordance with the respective national data protection regulations of Austria, Sweden and Switzerland. In addition to these national data protection regulations, directive 95/46/EC of the European Parliament (Ref.3: Directive 95/46/EC) shall apply in its latest version. If any veritable changes in European and/or national legislation on data protection will occur during the duration of the project, these will apply. Participating end users and test subjects shall, if they so request, be given access to the latest versions of both European directives and national acts on data protection.

5.1 National regulations

As the vast majority of the project's end-user involvement and field trials will be conducted in Austria, Sweden and Switzerland, respective national regulations on personal data protection will apply in order to protect the integrity of any end-user, interviewee and/or test subject participating in the project.

5.1.1 Austrian Federal Act concerning the Protection of Personal Data

(Datenschutzgesetz 2000 – DSG 2000)

Any resident of Austria, participating in the iWalkActive project as end-user, interviewee and/or test subject, is granted personal integrity under the Austrian Federal Act concerning the Protection of Personal Data (Appendix B1.1).

5.1.2 Swedish Personal Data Act

(Personuppgiftslag 1998:204)

Any resident of Sweden, participating in the iWalkActive project as end-user, interviewee and/or test subject, is granted personal integrity under the Swedish Personal Data Act (Appendix B1.2).

5.1.3 Swiss Federal Act on Data Protection

(235.1 Bundesgesetz über den Datenschutz)

Any resident of Switzerland, participating in the iWalkActive project as end-user, interviewee and/or test subject, is granted personal integrity under the Swiss Federal Act on Data Protection (Appendix B1.3).

5.2 European regulations

In the event that any person not living in Austria, Sweden or Switzerland would participate in the iWalkActive project, the following regulations on personal data protection will apply in order to protect the integrity of any end-user, interviewee and/or test subject participating in the project.

5.2.1 Directive 95/46/EC of the European Council

(Directive 95/46/EC of the European Council)

Any resident of the EU, participating in the iWalkActive project as an end-user, interviewee and/or test subject, is granted personal integrity under Directive 95/46/EC of the European Council.

5.3 Data Protection Agreement

The Data Protection Agreement is a document that must be signed by all project partners in order to assure that the recorded data will only be used for the foreseen research objectives.

Please see Appendix C.

6 Protection from Harm & eventual Insurance

6.1 Protection from Harm

Researchers and project partners must make every effort to minimize the risks of any harm, either physical or psychological, arising for any participant, researcher, project partner, institution, funding body or other person.

The project should carry out a risk analysis and, where significant risks are identified, should specify a risk management and harm alleviation strategy.

Where harm does nevertheless arise in the course of research, researchers should take remedial steps.

Participants should be given information as to whom they may contact in the event of any issues arising in the course of the research that cannot be resolved with members of the project team.

6.2 Insurance

When concrete plans for the end user involvement have been created, these plans will be verified with the legal departments of the project partners in order to evaluate if any additional insurance for the test subjects is required.

All participants and test subjects should be informed about the status of insurance before they take part in the field trials.

References

1. Usability Professionals' Association (UPA): "What is User-Centered Design?" http://www.upassoc.org/usability_resources/about_usability/what_is_ucd.html
2. Tom L. Beauchamp and James F. Childress: "Principles of Biomedical Ethics" Sixth Edition; OUP USA 2008
3. EUR Lex 1: "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" http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31995L0046:EN:HTML

Appendix A Informed Consent

Please see document *"Appendix_A_Informed_Consent.pdf"*.

Appendix B National Acts on Data Protection

B.1. Austrian Federal Act concerning the Protection of Personal Data

(Datenschutzgesetz 2000 – DSG 2000)

Please see document *"AppB1_Austrian_Federal_Act_Protection_of_Personal_Data.pdf"*.

B.2. Swedish Personal Data Act

(Personuppgiftslag 1998:204)

Please see document *"AppB2_Swedish_Personal_Data_Act.pdf"*.

B.3. Swiss Federal Act on Data Protection

(SR 235.1)

Please see document *"AppB3_Swiss_Federal_Act_on_Data_Protection.pdf"*.

Appendix C Data Protection Agreement

Please see document *"Appendix_C_Data_Protection_Agreement.pdf"*.