Deliverable 4.1

Validation & Testing concept

Project Number	AAL 2017 – AAL packages / integrated solutions
Project Name	Ella4Life
Duration	June 1st 2018 – May 31st 2021 (36 Months)
Coordinator	Virtask
Document ID	D 4.1
Release Number / Date	V1.0 / 31. 05.2021
Checked and released by	Patty-Lou Middel
Document Type	Project Deliverable
Original Due Date	01 October 2019
Dissemination Level	Public
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Abstract
The purpose of D 4.1 is to prove that Ella4Life improves self-management, wellbeing and independence of older people and in particular older people with a chronic condition. Extensive field tests are carried out to test the effectiveness of the system. Each test is evaluated through a survey. The survey is the same in all countries and for all participants. This enables a uniform evaluation. To make this possible, this validation & test concept is required.

What is new in this Version
This is the final version of the deliverable.

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The Ella4Life project is Co-funded by the European AAL Joint Programme

Version	***Date***	***Changes***	***Name***	***Organisation***
0.1	2019-08-07	Initial Creation	Clemens Nieke	HSL
0.2/3	2019-09-12	Enhanced chapters 3-5	Martin Wüthrich	HSL
0.4	2019-10-01	Internal review	Clemens Nieke	HSL
0.5	2121-05-19	Final touch and review	Edith Birrer	HSL

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Content:

1 Executive Summary

D4.1 "Validation & Testing Concept" describes the evaluation framework that partners involved in WP 4 "System validation & evaluation" will use to validate the feasibility, functionality, acceptability and usability of the Ella4Life system.

The document describes in detail the methodology and expected outcomes of these field trials. The main results of these studies are the feedback provided by end users. This document also describes potential risks that may arise during these studies and the plans set to overcome them.

2 Introduction

A great challenge of the Ella4Life project is to provide a human-centred perspective that can be integrated in the main development cycles of the system. The active involvement of users and a clear understanding of context of use are the key strengths to overcome the main barriers in applying technology for seniors. This strategy represents the core of the User Centred Design (UCD), a design philosophy which encompasses various methodologies and techniques which seek to involve the end-user in the design process, with the end-user being defined as the '*person who will ultimately be using the product*'. The goal of UCD is to optimise the usability, human factors and hence the user experience (UX) of a product. The International Standards Organisation standard ISO 9241-210 extended the definition of UCD to "address impacts on a number of stakeholders, not just those typically considered as users", referring to the design approach as Human Centred Design (HCD). The terms HCD and UCD are used synonymously and as such the term UCD will continue to be used throughout this document.

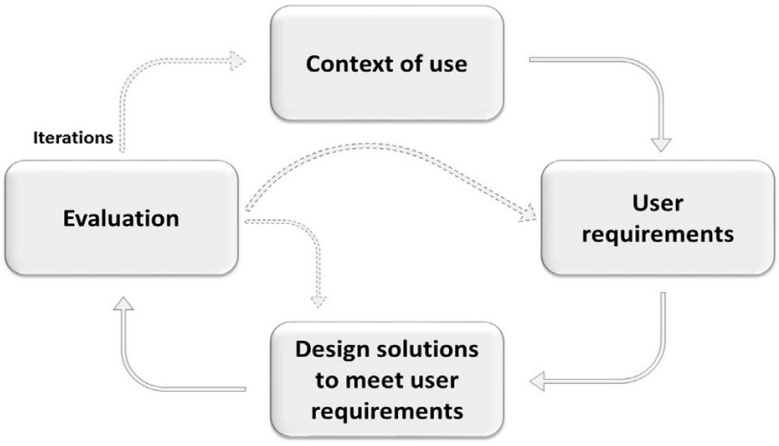


Figure 1 The UCD approach

The UCD approach is a process consisting of four fundamental activities related to user involvement (Figure 1). The ella4Life project implemented this approach as described in the following bullet points:

a) User groups are specified, and the context of use is described (Activity 1: understand and specify the context of use). This activity is covered in WP 4 "System validation & evaluation".

b) A set of specific requirements is defined to create a degree of fit between device and user (Activity 2: specify the user requirements). This step is performed within the WP2 "Requirements & system specification".

c) The design prototype is produced based on these specifications and it is presented to the user in the form of user testing (Activity 3: Produce design solutions to meet requirement). It is the core of WP3 "Service Development & Integration".

d) Once feedbacks from the user have been received, the process begins again until all user requirements have been met (Activity 4: evaluation). The evaluation phase is the objective of WP4 "system validation & evaluation".

As for its iterative nature, the process requires that information is gathered from the user at each step and actions are taken based on that, in order to interpret the information correctly.

During the project lifetime, 4 different iterations will be performed.

Based on the UCD approach, this document is related only to the evaluation phase, and it is aimed to discuss activities that will be covered within the WP 4 "System validation & evaluations".

The objectives of the pilot evaluations are mainly to assess the feasibility, usability, acceptance and functionality of the system and the ability of the potential target user to use the system and receive valuable information from it to help them address the complex needs of elderly people.

The project team will measure this by using the following key performance indicators (KPI):

Our quantitative indicators:

1. More self-management by having less planned and unplanned involvement of professionals in care as well as in cure.
2. Fewer escalations, for example, fewer exacerbations in users suffering from COPD.

Our qualitative indicators:

1. the feeling of wellbeing
2. the feeling of overload or strain for informal caretakers
3. the extent to which people (users, informal caregivers, and professional caregivers) would recommend Ella4Life (NPS)

The pilot evaluations will be set up in Switzerland. After the first experiences there, the Netherlands, Poland, and Romania will follow.
This multi-site design will allow evaluating the Ell4Life system in different social and cultural contexts. Overall, the multinational approach proposed will ensure wide acceptability of the developed technology and will prepare the possibility of Europe-wide deployment after project life.

2.1 Technical evaluation

The advantages of these systems are:

- All necessary base functions like camera, microphone, speakers, and touch screen are present on the tablet.
- The size of the screen is ideal for the application.
- The compact systems minimize the amount of wiring.
- The system works well without the use of mouse and keyboard (this means that the tablet does not look like a computer).
- Tablets are more mobile than most other devices.
- Additional sensors can be easily integrated in the overall system.

2.1.1 Equipment requirement

Anne works on a tablet that runs the operating system Microsoft Windows 10.

Smartphones have operating systems of Apple (iOS) or Google (Android). This is especially required for the Emma App.

The blood pressure monitor is a commercial product from the company Microlife. The device has a Bluetooth interface with which it connects to the Emma App. The interface exists already and must therefore only be tested for functionality within the framework of the E4L project.

In the second iteration, further sensors will be added: sensors for the bathtubs and armchairs. They will be added after the MTR.

2.1.2 Equipment availability

The entire project has a duration of three years (2018 – 2021). The user test period will also take three years divided into multiple phases. In the budget of the project, the purchase of new hardware is considered.

The hardware budget is part of the end-user organizations' budget. In May 2019, HSL ordered for their trials in Switzerland three Microsoft Surface tablets and three Microlife blood-pressure monitoring devices. In the Netherlands, some further systems were purchased. However, the main determinations are necessary after the MTR. Then the extensive end-user tests begin.

2.2 Trial evaluation

The Ella4Life consortium respects the importance of testing and thus dedicates in total 36 project months to all kinds of test iterations (functional, focus and control groups and field trials). Comprehensive testing and evaluation will be performed by in total minimum of 300 end-users in 4 pilot locations during the whole Ella4Life project duration in several iterations and stages, as it is required in User Centred Design approach.

A sample of 330 end-users will be enrolled. For the pilot period, we have at least the intended minimum number of end-users included. These participants will be a real reflection of the demographic structure in the country concerned.

Netherland:	Pilot group minimum	100 end-users
	Control group minimum	up to 100 end-users
Romania:	Pilot group minimum	100 end-users
Poland:	Pilot group minimum	100 end-users
Switzerland:	Lab-test users	30-50 end-users

Inclusion criteria for the enrolment are described in the table below.

Target	Characteristics	Measure
Older Adult (55+)	• Volunteers living independently who have/wish to have a healthy lifestyle, and who allow monitoring of their health status. • Presence of some problems with the blood pressure • Overall good health condition	• The person must measure their blood pressure regularly. • Trained support staff (e.g. nurses, educators, psychologists, etc) will assist the persons if necessary
Informal Caregivers	• informal caregiver of a person	• Caregiver Burden Inventory

Table 1 Inclusion criteria

The presence of at least one of the following criteria will exclude the user from the enrolment:

- Lack of written informed consent (both for older adult and informal caregiver).
- Serious heart problems requiring constant medical monitoring.
- Presence of several physical illness or disabilities that could be aggravated using a speech-controlled system.

2.3 Recruitment procedure

The recruitment plan will be similar for all iterations. The end user will be recruited in each site through clinical centres, municipality recreational centres, and voluntary organizations, presentations during meetings and by personal contacts. Initial screening will include a short phone interview, intended to exclude participants that do not fit the criteria for participation (i.e., age, independent living, serious heart problems). Eligible participants will then be invited to come to the pilot sites for further discussion. When participants first arrive to the centre, study personnel will explain the study to them including all assessments, procedures, risks, and benefits. The participant will be asked to sign an informed consent prior to any testing done.

2.4 Study Design and Methods

The lab test will run in a personal setting. All other end user trials will run by minimum 6 week in a private environment.

The field test will be managed by skilled personnel and researchers that will guarantee both the supervision of the tests by specialized staff and the detailed measurement of the first interaction between users and the first system prototype. Data coming from this stage will be used to assess and/or refine achieved S/T requirements and come to the second prototype for the second round of field trial.
The first field trial procedure consists of the following phases:

- Recruitment based on specific inclusion and exclusion criteria.
- Instruction Phase. In this phase both older adults and caregivers will be instructed to use the system's functionalities.
- Evaluation of the interaction.

Quantitative and qualitative methods will be used in this first iteration.

The quantitative and standardized instruments to use are:

1. The SF-36™ Health Survey. It is a brief, reliable measure of overall health status. It is useful in large population health surveys and has been used extensively as a screening tool.
2. The meCUE 2.0 questionnaire. meCUE is a freely available, scientifically founded questionnaire, which focuses on the modular acquisition of user-centred reviews and their experience of interactive technical products. meCUE is based on the component model of User Experience (CUE-Model) and allows for the modular evaluation of central aspects of User Experience.
3. Caregiver Burden Inventory. It is a 24-item multi-dimensional questionnaire measuring caregiver burden with 5 subscales: (a) Time Dependence; (b) Developmental; (c) Behaviour; (d) Physical Burden; (e) Social Burden; (f) Emotional Burden. Scores for each item are evaluated using a 5-point Likert scale ranging from 0 (not at all disruptive) to 4 (very

disruptive). All the scores on the 24-item scale are summed and a total score >36 indicates a risk of "burning out" whereas scores near or slightly above 24 indicate a need to seek some form of respite care.

Each instrument will be verbally administered in a face-to-face session by a trained interviewer who will fill the responses on a paper version of the questionnaire.

The table below summarizes the different methods that will be used to assess the interaction between the elderly user and the system:

Dimension	**Method**	**Start/Single trial**	**End of trial**
Socio-Demographics Data	ad hoc items	X	
Health Status	SF-36™	X	
User-centred review	meCUE 2.0	X	X

Table 2 Methods to gather data from elderly adults

The table below summarizes the different methods that will be used to assess the informal caregiver burden:

Dimension	**Method**	**Start/Single trial**	**End of trial**
Socio-Demographics Data	ad hoc items	X	
Burden	Caregiver Burden Inventory	X	X

Table 3 Methods to gather data from cargivers

2.5 Evaluation Outcomes

The evaluation will be using the following key performance indicators (KPI):

Quantitative indicators:

1. More self-management by having less planned and unplanned involvement of professionals in care as well as in cure.
2. Fewer escalations, for example, fewer exacerbations in users suffering from COPD.

Qualitative indicators:

1. Feeling of wellbeing
2. Feeling of overload or strain for informal caretakers
3. Extend to which people (users, informal caregivers, and professional caregivers) would recommend Ella4Life (NPS).

The main goal is to provide a solution for the consumer market that perfectly connects to the world of the professionals. Therefore, research into the acceptance is necessary to be able to build the proper marketing strategy.

The questions we want to be answered are:

1. Is there a connection between the age of the elderly people and their willingness to use Ella4Life?
   For example, when people are relatively vital and younger, between 55 and 70, will they be willing to use Ella4Life and follow her instructions?

2. Is there a connection between the presence of chronic diseases and the willingness to use Ella4Life?
   For example, are people not having a chronic disease willing to use Ella4Life to stay healthier?

3. Is there a connection between the age of the elderly people and their need to be assisted in the use of technical and/or digital devices?
   For example, when people get older will they get problems handling all the electronic and digital devices and will they thus be willing to use Ella4Life and will they be able to learn how to communicate with her?

4. Overall, when Ella4Life contributes to a healthier lifestyle, more self-management and supports people in their wish to stay independent, what will people be willing to invest, financially as well as in time and attention in a system like Ella4Life to make it possible to stay independent and self-supporting?

3 Ethical Issues

Ella4Life touches on sensitive ethical issues because direct user participation is seen as a key aspect within the project. End-users will provide private data about their daily routine, limitations and so forth. All ethical issues that this project may be exposed to will be handled by the partners in their home countries with the local ethical committees. In particular, the work will be subject to the following ethical-related directives, regulations and international conventions and declarations:

- The Charter of Fundamental Rights of the EU (2000/c 364/01)
- REGULATION (EU) 2016/679 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 27 April 2016 on the protection of natural persons regarding

the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation)[1]

- The reform of the data protection rules that was launched in January 2012 is not in force yet, but we will consider it and apply once it will be in force.
- Directive 2001/20/EC of 4 April 2001 on clinical good practice
- Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions
- Opinions of the European Group on Ethics in Science and New Technologies, including in particular:
  - Opinion of the European group on ethics in science and new technologies to the European commission, number 7, May 21st, 1996
  - Opinions of the European Group on Ethics in Science and New technologies (as from 1998)
- Helsinki Declaration in its latest version

Research ethics requires that all research involving human participants, personal data, or human tissue should be reviewed and research ethics approval obtained before data gathering commences. Each partner involved in the trial evaluations will apply for ethical approval from Local Ethical Committees, completing the appropriate application form and submits it to their Ethics Administrator.

3.1 Informed consent

Potential participants will be asked to express their interest to the staff after they have received the recruitment material. Then personal or group meetings will be arranged towards clarifying any misunderstanding that may occur. Only then, those who already have decided to participate will be asked to sign the consent letter and will be informed of the following actions. Those who will have not reached to a decision yet, will be asked to return the signed consent in the future or to inform the staff for their negative decision.

The specifications that an informed consent should fulfil are the following:

- Ensure that the potential participants are given ample opportunity to understand the nature, purpose, and the anticipated consequences.

[1] REGULATION (EU) 2016/679 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 27 April 2016, source: http://ec.europa.eu/justice/data-protection/reform/files/regulation_oj_en.pdf

- Keep adequate records of when, how and from who consent was obtained.
- Take care about the use of images, video and sound recordings containing personal data.
- Remain alert to the possibility that potential participants may lack legal capacity for informed consent.
- Avoid intentional deception of clients.
- Support the self-determination of clients; while at the same time remain alert to potential limits placed upon self-determination by personal characteristics or by externally imposed circumstances.
- Ensure from the first contact that clients are aware of their right to withdraw at any time from the receipt of research participation.
- Comply with requests by clients who are withdrawing from research participation that any data by which they might be personally identified, including recordings, be destroyed.

Clear explanations were given to the participants about the contents of the document:

- Summary of the objectives of the Ella4Life project
- Information about the participants' rights and obligations, as well as the nature of the tasks/activities they are required to undertake.
- Signature of the informed consent form

Chapter 7.2 "Annex 2: Informed Consent" contains the informed consent form in English as an example.

3.2 Privacy and Data Protection

The consortium agreed to respect and protect human dignity, including informational self-determination in line with the principles and case law of the European Convention of Human Rights and the EU Charter of Fundamental Rights[2]. Also, the directives issued for ICT developments by the UN International Action Plan on Ageing will be followed strictly.
The measurement, processing and storage of personal data are subject to the European Data Protection Directive and the respective national implementations thereof. These regulations will be taken into consideration in the project and its pilot implementations by all of the

[2] Human Dignity: article 1; The rights of the elderly: article 12 and article 25

partner organisations. Additionally, the data protection directive for electronic communications 2002/58/EC and Article 8 of the European Convention on Human Rights have to be considered. The consortium building the integrated Ella4Life will direct special attention to identify critical privacy and confidentiality requirements of data with respect to information flow security.

4 Site Profiles Description

4.1 Livelife (LLI)

Expertise: Distribution of specialized health services and products to the end-users, promotion of health and a healthy lifestyle and life enriching, Home care services. Performs directly for over 70,000 households, helping elderly people with practical solutions and advice about housing, care and welfare. Indirectly, Lifelife provides healthy livestyle workshops and education for several homecare companies with 1 mio. elderly end-users. Lifelive is in continuous contact with end-users for discovering their needs, and with several professionals and developers from the elderly social welfare industry. Skills include international PR, marketing and sales, market research activities, marketing and sales management, quality management, field testing.

4.2 Ana Aslan International Foundation (ANA)

Is a non-profit research, education, and high-profile medical services organization, with special expertise in Aging and Brain Aging. Its mission is to integrate scientific progress into the medical and social practice of elderly care. Furthermore, ANA has expanded its expertise in the field of applied ICT technologies for frail and dependent elderly, so that it not only helps prevent the aging related pathologies but promotes an active and healthy ageing. In the past 10 years, ANA has accumulated extensive research, management, and innovative experience as medical partner and pilot site in EU funded projecta within FP6-IST-STREP (K4CARE and SHARE-it), AAL-Ambient

Assisted Living (specifically: MobileSage, CONFIDENCE, Mobile.Old, CarerSupport, StayActive, MyMate, SeniorTV, TSBank, PETAL), FP7-CIP-ICT (AgeingWell and E-NO FALLS) and LLP-Grundtvig (LiveWell). In these projects, ANA fulfilled various tasks such as end-user profiling and specifications, technical and functional specifications, the assessment of end-users' compliance to smart technology, the evaluation and validation of various smart technology prototypes in cooperation with elderly voluntary end-users. It also shared a high-level expertise in the related ethical issues.

4.3 Vicino Luzern (VIC)

Vicino Luzern is a non-profit association with over 20 member institutions, all active in delivering elderly care services for the citizens of Lucerne, a city in central Switzerland with around 80'000 inhabitants. These institutions have joined forces with one major goal: To cooperate and communicate together to improve the quality of life of elderly people living in the city of Lucerne and, if ever possible, to allow them to live independently and securely at home for as long as possible. This is remarkable as some of these institutions used to be competitors but decided that the overall service offer for the elderly people and their informal caregivers could be improved and more efficiently coordinated if they work together. Their claim is now: "Getting old in your quarter".
The range of different institutions working together reaches from the biggest provider of ambulant care services (Spitex), social services providers (Caritas, ProSenectute, catholic and protestant churches), emergency calling services (Swiss Red Cross), the largest operator of elderly care homes (Viva AG), to a day-care facility for people with dementia (Roter Faden) and the city of Lucerne itself.
Finally, with abl (Allgemeine Baugenossenschaft Luzern), the largest cooperative housing association in the region supports Vicino Luzern. To implement and test the newly created community care concept, the abl has initiated a pilot project in Lucerne. On a major construction site in the middle of the city, the so called "Himmelrich", 260 new apartments of different sizes are built for a heterogeneous target group. The idea is to create a diverse community with people of different backgrounds and ages and foster volunteering to support elderly people living at home. If the pilot proves successful, the Vicino concept is planned to scale to other quarters of Lucerne and hopefully also out of the city into the villages nearby.
Besides the member institutions, Vicino employs social workers with competences in socio-cultural animation to build up the neighborhood

network and link to the professional services available in Lucerne. The Lucerne University of Applied Sciences also supports this community building procedure by organizing a "Digitreff" once a week where volunteers help people of the Himmelrich to solve personal "digital" challenges with their Laptops, Smartphones and Tablets (digital literacy services). Further, the iHomeLab acts as coach for assistive technology.

4.4 Muflon Sp. Z.o.o. (MUF)

Muflon has been providing care services continuously since 2008, rehabilitation and sanatorium home and care for elderly people in homes) in the province of Silesia, Poland. About 9,000 people a year use Muflon services at homes each year. As part of therapeutic stays, about 3,000 people use ORW Muflon (a sanatorium) per year. Muflon is preparing to set up a Research Centre for multifacious pain treatment, especially chronic pain. In the E4L project, Muflon will participate in end-user requirements definition and later in end-user evaluation as well as testing prototypes and the final product of the Ella4Life system.

5 Risk Management

Pilot project risks have the potential to affect project goals and pilot goals.

The project partners have defined risk as any event which is likely to adversely affect the ability of the project to achieve the defined objectives. Pre-defined procedures will be considered to minimise the possible occurrence of adverse events in the construction and deployment of the project.

Category	Risk	Level	Impact	Contingency Plan
End-users' enrolment	Drop-outs and the failure to attend the study.	Medium	Medium	A reserve list of potential users that meet the inclusion criteria will be constructed in each site.
Acceptance	The new technological solution does not match to	Low	Medium	The previous knowledge and experience of the partners will be used during the pilot evaluations

	the user's expectations in terms of comfort.			to avoid any problem in respect to the end users. Moreover, during the pilot the participant will be specifically asked about the systems and any feedback provided will be delivered to the technical team for implementation.
Functionality	The system is unable to collect data.	Low	High	During the functional trials, the functionality of the system will be validated long before the system is used with potential users, this to ensure that the system is stable in terms of data collection, data processing and data analysis and presentation.
Feasibility	The participants are unable to use the system alone and unable to operate the system.	Medium	Medium	The participants will require assistance in the beginning and detailed explanation to be able to operate the system alone. Personnel will explain the operation to the subjects; Participants will also receive a written manual.
Usability	The participation of the users is low as participants do not regard the system to be useful for them.	Low	Medium	The validation sites have experience in conducting this kind of activities and they have direct links with end-users and stakeholders. Devoted dissemination campaigns and publicity will be carried out before the start of the validation phase, to ensure a wide participation. Moreover, experts in gerontology, psychology and geriatrics will be involved to motivate the participants and avoid drop-outs.
	The participants do not think they will require such a system and therefore do not intend to use it.	low	medium	The system will be designed based on user needs as are expressed in the literature and based on the user requirements. Therefore, we do not expect such a scenario. In the case it will occur, the teams will explain the usefulness of the system to the participants and show the many

				ways it can help in improving daily life.

6 Definitions, Acronyms and Abbreviations

Ella4Life - Acronym of the current project: "Ella4Life – your Virtual Personal Assistant for home and on the road"

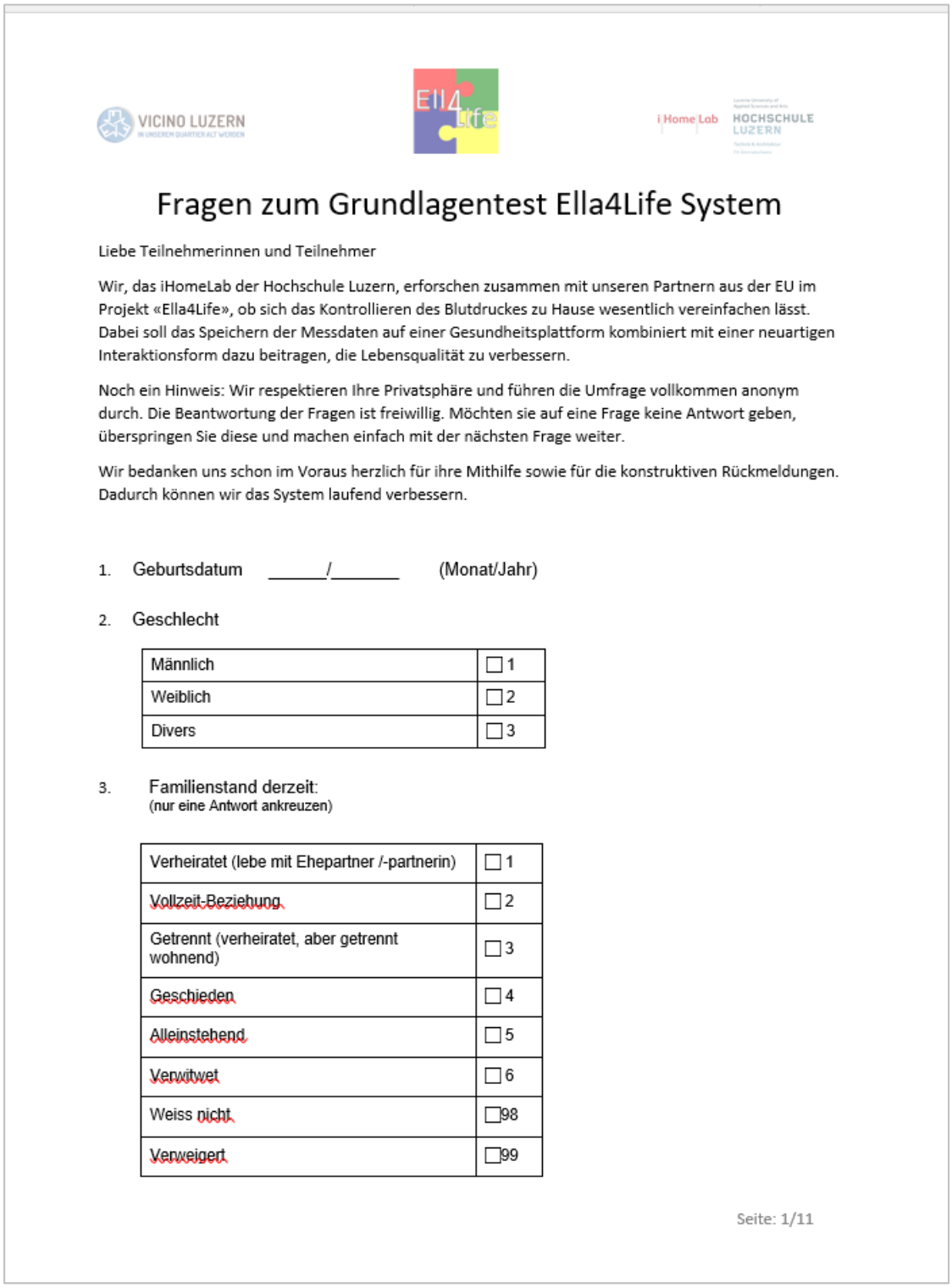
AAL Programme - Active Assistive Living Programme

ICT - Information and Communication Technology

7 Appendix

7.1 Annex 1: Questionnaires

The basic German Version



VICINO LUZERN

i Home Lab HOCHSCHULE LUZERN

Fragen zum Grundlagentest Ella4Life System

Liebe Teilnehmerinnen und Teilnehmer

Wir, das iHomeLab der Hochschule Luzern, erforschen zusammen mit unseren Partnern aus der EU im Projekt «Ella4Life», ob sich das Kontrollieren des Blutdruckes zu Hause wesentlich vereinfachen lässt. Dabei soll das Speichern der Messdaten auf einer Gesundheitsplattform kombiniert mit einer neuartigen Interaktionsform dazu beitragen, die Lebensqualität zu verbessern.

Noch ein Hinweis: Wir respektieren Ihre Privatsphäre und führen die Umfrage vollkommen anonym durch. Die Beantwortung der Fragen ist freiwillig. Möchten sie auf eine Frage keine Antwort geben, überspringen Sie diese und machen einfach mit der nächsten Frage weiter.

Wir bedanken uns schon im Voraus herzlich für ihre Mithilfe sowie für die konstruktiven Rückmeldungen. Dadurch können wir das System laufend verbessern.

1. Geburtsdatum _____/_____ (Monat/Jahr)

2. Geschlecht

Männlich	☐ 1
Weiblich	☐ 2
Divers	☐ 3

3. Familienstand derzeit:
(nur eine Antwort ankreuzen)

Verheiratet (lebe mit Ehepartner /-partnerin)	☐ 1
Vollzeit-Beziehung	☐ 2
Getrennt (verheiratet, aber getrennt wohnend)	☐ 3
Geschieden	☐ 4
Alleinstehend	☐ 5
Verwitwet	☐ 6
Weiss nicht	☐ 98
Verweigert	☐ 99

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4. Welches der folgenden Bildungsniveaus haben Sie erreicht?
(nur eine Antwort ankreuzen)

Keine Ausbildung	☐ 0
Grundschulbildung	☐ 1
Sekundarschulbildung	☐ 2
Tertiäre Bildung (Universität oder Weiterbildungsniveau)	☐ 3
Weiss nicht	☐ 98
Verweigert	☐ 99

5. Zahl der Jahre in Ausbildung insgesamt _____

6. Bitte geben Sie Ihre aktuelle Arbeitssituation an:
(Mehrfachnennungen möglich):

6.1 im Ruhestand	☐ 1
6.2 arbeite Vollzeit	☐ 2
6.3 arbeite Teilzeit	☐ 3
6.4 Arbeitslos	☐ 4
6.5 Heimarbeit	☐ 5
6.6 Weiss nicht	☐ 98
6.7 Verweigert	☐ 99

7. Was sind Ihre persönlichen Einkommensquellen?
(Mehrfachnennungen möglich)

7.1 Arbeit	☐ 1
7.2 Pension / Rente	☐ 2
7.3 Noch nicht realisierte Erträge	☐ 3
7.4 Hilfe von Verwandten	☐ 4
7.5 Sozialhilfe	☐ 5
7.6 Andere	☐ 6
7.7 Weiss nicht	☐ 98
7.8 Verweigert	☐ 99

8. Wenn andere, bitte spezifizieren: _____

9. Wer lebt in Ihrem Zuhause mit Ihnen?
(Mehrfachnennungen möglich)

Kategorie	Code	Anzahl der ...
9.1. Niemand	☐ 1	---------
9.2. Ehepartner / Partner	☐ 2	
9.3. Söhne und Töchter	☐ 3	
9.4. Enkelkinder	☐ 4	
9.5. Kinder des Ehegatten	☐ 5	
9.6. Brüder, Schwestern	☐ 6	
9.7. Mutter, Vater	☐ 7	
9.8. Bezahlte Betreuungsperson (nicht verwandt)	☐ 8	
9.9. Andere	☐ 9	
9.10. Keine Angabe	☐ 99	

10. Wenn anders, bitte spezifizieren _____

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11. Wie würden Sie Ihren Gesundheitszustand im Allgemeinen beschreiben?
(nur eine Antwort ankreuzen)

11.1 Ausgezeichnet	☐ 1
11.2 Sehr gut	☐ 2
11.3 Gut	☐ 3
11.4 Weniger gut	☐ 4
11.5 Schlecht	☐ 5

12. Im Vergleich zum vergangenen Jahr, wie würden Sie Ihren derzeitigen Gesundheitszustand beschreiben?
(nur eine Antwort ankreuzen)

12.1 Derzeit viel besser als vor einem Jahr	☐ 1
12.2 Derzeit etwas besser als vor einem Jahr	☐ 2
12.3 Etwa so wie vor einem Jahr	☐ 3
12.4 Derzeit etwas schlechter als vor einem Jahr	☐ 4
12.5 Derzeit viele schlechter als vor einem Jahr	☐ 5

Die folgenden Fragen beziehen sich auf mögliche Tätigkeiten im Alltag. Sind Sie durch Ihren derzeitigen Gesundheitszustand bei diesen Tätigkeiten eingeschränkt? Wenn ja, wie stark?
(Nur eine Antwort pro Zeile ankreuzen)

	Ja, sehr stark	Ja, etwas	Nein
13. Anstrengende Tätigkeiten wie schnell laufen, schwere Gegenstände heben, anstrengenden Sport treiben	☐ 1	☐ 2	☐ 3
14. Mittelschwere Tätigkeiten, z.B. eine Tisch verschieben, stausaugen, kegeln, Golf spielen	☐ 1	☐ 2	☐ 3
15. Einkaufstaschen heben oder tragen	☐ 1	☐ 2	☐ 3
16. Mehrere Treppenabsätze steigen	☐ 1	☐ 2	☐ 3

	Ja, sehr stark	Ja, etwas	Nein
17. Einen Treppenabsatz steigen	☐1	☐2	☐3
18. Sich beugen, knien oder bücken	☐1	☐2	☐3
19. Mehr als einen Kilometer zu Fuss gehen	☐1	☐2	☐3
20. Mehrere Strassenkreuzungen weit zu Fuss gehen	☐1	☐2	☐3
21. Eine Strassenkreuzung weit zu Fuss gehen	☐1	☐2	☐3
22. sich baden oder anziehen	☐1	☐2	☐3

Bestanden in den vergangenen 4 Wochen aufgrund der körperlichen Gesundheit irgendwelche Einschränkungen bei der Arbeit oder anderen alltäglichen Tätigkeiten im Beruf bzw. zu Hause?
(nur eine Antwort pro Zeile ankreuzen)

	Ja	Nein
23. Ich konnte nicht so lange tätig sein	☐1	☐2
24. Sie haben weniger gearbeitet, als Sie wollten?	☐1	☐2
25. Ich konnte nur bestimmte Dinge tun	☐1	☐2
26. Ich hatte Schwierigkeiten bei der Ausführung (z.B. ich musste mich besonders anstrengen)	☐1	☐2

Hatten Sie in den vergangenen 4 Wochen aufgrund seelischer Probleme irgendwelche Schwierigkeiten bei der Arbeit oder anderen alltäglichen Tätigkeiten im Beruf bzw. zu Hause z.B. weil Sie sich niedergeschlagen oder ängstlich fühlten?
(nur eine Antwort pro Zeile ankreuzen)

	Ja	Nein
27. Ich konnte nicht so lange wie üblich tätig sein	☐1	☐2
28. Sie haben weniger gearbeitet, als Sie wollten?	☐1	☐2
29. Ich konnte nicht so sorgfältig wie üblich arbeiten	☐1	☐2

30. Wie sehr haben Ihre körperliche Gesundheit oder seelischen Probleme in den vergangenen 4 Wochen Ihre normalen Kontakte zu Familienangehörigen, Freunden, Nachbarn oder zum Bekanntenkreis beeinträchtigt?
(Nur eine Antwort ankreuzen)

30.1 Überhaupt nicht	☐ 1
30.2 Etwas	☐ 2
30.3 Mässig	☐ 3
30.4 Ziemlich	☐ 4
30.5 Sehr	☐ 5

31. Wie stark waren Ihre Schmerzen in den vergangenen 4 Wochen?
(Nur eine Antwort ankreuzen)

31.1 Ich hatte keine Schmerzen	☐ 1
31.2 Sehr leicht	☐ 2
31.3 Leicht	☐ 3
31.4 Mässig	☐ 4
31.5 Stark	☐ 5
31.6 Sehr stark	☐ 6

32. Inwieweit haben die Schmerzen Sie in den vergangenen 4 Wochen bei der Ausübung Ihrer Alltagstätigkeiten zu Hause und im Beruf behindert
(Nur eine Antwort ankreuzen)

32.1 Überhaupt nicht	☐ 1
32.2 Ein bisschen	☐ 2
32.3 Mässig	☐ 3
32.4 Ziemlich	☐ 4
32.5 Stehr	☐ 5

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In den folgenden Fragen geht es darum, wie Sie sich fühlen und wie es Ihnen in den vergangenen 4 Wochen gegangen ist. (Bitte kreuzen Sie in jeder Zeile die Zahl an, die Ihrem Befinden am ehesten entspricht).
Wie oft waren Sie in den vergangenen 4 Wochen...:
(Nur eine Antwort pro Zeile ankreuzen)

	Immer	Meistens	Ziemlich oft	Manch-mal	Selten	Nie
33. ... voller Schwung	☐1	☐2	☐3	☐4	☐5	☐6
34 ... sehr nervös	☐1	☐2	☐3	☐4	☐5	☐6
35. ... so niedergeschlagen, dass Sie nichts aufheitern konnte?	☐1	☐2	☐3	☐4	☐5	☐6
36. ... ruhig und gelassen	☐1	☐2	☐3	☐4	☐5	☐6
37. ... voller Energie	☐1	☐2	☐3	☐4	☐5	☐6
38. ... entmutigt und traurig	☐1	☐2	☐3	☐4	☐5	☐6
39. ... erschöpft	☐1	☐2	☐3	☐4	☐5	☐6
40. ... glücklich	☐1	☐2	☐3	☐4	☐5	☐6
41. ... müde	☐1	☐2	☐3	☐4	☐5	☐6

42. Wie häufig haben Ihre körperliche Gesundheit oder seelischen Probleme in den vergangenen 4 Wochen Ihre Kontakte zu anderen Menschen (Besuche bei Freunden, Verwandten usw.) beeinträchtigt?
(Nur eine Antwort ankreuzen)

42.1 Immer	☐1
42.2 Meistens	☐2
42.3 Manchmal	☐3
42.4 Selten	☐4
42.5 Nie	☐5

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Inwieweit trifft jede der folgenden Aussagen auf Sie zu?
(Nur eine Antwort pro Zeile ankreuzen)

	Trifft ganz zu	Trifft weit-gehend zu	Weiss nicht	Trifft weitge-hend nicht zu	Trifft überhaupt nicht zu
43. Ich scheine etwas leichter als andere krank zu werden	☐1	☐2	☐3	☐4	☐5
44. Ich bin genauso gesund wie alle anderen, die ich kenne	☐1	☐2	☐3	☐4	☐5
45. Ich erwarte, dass meine Gesundheit nachlässt	☐1	☐2	☐3	☐4	☐5
46. Ich erfreue mich ausgezeichneter Gesundheit	☐1	☐2	☐3	☐4	☐5

Produktbewertung

Sie haben das neue System zur Selbstkontrolle des Blutdrucks getestet. Bitte bewerten sie das Produkt.
(Nur eine Antwort pro Zeile ankreuzen)

	stimme völlig zu	stimme zu	stimme eher zu	weder noch	lehne eher ab	lehne ab	lehne völlig ab
47. Das Produkt lässt sich einfach benutzen.	☐7	☐6	☐5	☐4	☐3	☐2	☐1
48. Die Funktionen des Produkts sind genau richtig für meine Ziele.	☐7	☐6	☐5	☐4	☐3	☐2	☐1
49. Es wird schnell klar, wie man das Produkt bedienen muss.	☐7	☐6	☐5	☐4	☐3	☐2	☐1
50. Ich halte das Produkt für absolut nützlich.	☐7	☐6	☐5	☐4	☐3	☐2	☐1
51. Die Bedienung des Produkts ist verständlich.	☐7	☐6	☐5	☐4	☐3	☐2	☐1
52. Mithilfe des Produkts kann ich meine Ziele erreichen.	☐7	☐6	☐5	☐4	☐3	☐2	☐1
53. Das Produkt ist kreativ gestaltet.	☐7	☐6	☐5	☐4	☐3	☐2	☐1

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	stimme völlig zu	stimme zu	stimme eher zu	weder noch	lehne eher ab	lehne ab	lehne völlig ab
54. Das Produkt verleiht mir ein höheres Ansehen.	☐7	☐6	☐5	☐4	☐3	☐2	☐1
55. Ohne das Produkt kann ich nicht leben.	☐7	☐6	☐5	☐4	☐3	☐2	☐1
56. Das Design wirkt attraktiv.	☐7	☐6	☐5	☐4	☐3	☐2	☐1
57. Durch das Produkt werde ich anders wahrgenommen.	☐7	☐6	☐5	☐4	☐3	☐2	☐1
58. Das Produkt ist wie ein Freund für mich.	☐7	☐6	☐5	☐4	☐3	☐2	☐1
59. Das Produkt ist stilvoll.	☐7	☐6	☐5	☐4	☐3	☐2	☐1
60. Wenn ich das Produkt verlieren würde, würde für mich eine Welt zusammenbrechen.	☐7	☐6	☐5	☐4	☐3	☐2	☐1
61. Meine Freunde können wegen des Produkts ruhig neidisch auf mich sein.	☐7	☐6	☐5	☐4	☐3	☐2	☐1
62. Das Produkt beschwingt mich.	☐7	☐6	☐5	☐4	☐3	☐2	☐1
63. Das Produkt macht mich müde.	☐7	☐6	☐5	☐4	☐3	☐2	☐1
64. Das Produkt nervt mich.	☐7	☐6	☐5	☐4	☐3	☐2	☐1
65. Das Produkt entspannt mich.	☐7	☐6	☐5	☐4	☐3	☐2	☐1
66. Durch das Produkt fühle ich mich erschöpft.	☐7	☐6	☐5	☐4	☐3	☐2	☐1
67. Durch das Produkt fühle ich mich ausgeglichen.	☐7	☐6	☐5	☐4	☐3	☐2	☐1
68. Das Produkt frustriert mich.	☐7	☐6	☐5	☐4	☐3	☐2	☐1
69. Das Produkt stimmt mich euphorisch.	☐7	☐6	☐5	☐4	☐3	☐2	☐1
70. Durch das Produkt fühle ich mich passiv.	☐7	☐6	☐5	☐4	☐3	☐2	☐1

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	stimme völlig zu	stimme zu	stimme eher zu	weder noch	lehne eher ab	lehne ab	lehne völlig ab
71. Das Produkt beruhigt mich.	☐7	☐6	☐5	☐4	☐3	☐2	☐1
72. Durch das Produkt fühle ich mich fröhlich.	☐7	☐6	☐5	☐4	☐3	☐2	☐1
73. Das Produkt verärgert mich.	☐7	☐6	☐5	☐4	☐3	☐2	☐1
74. Wenn ich könnte, würde ich das Produkt täglich nutzen.	☐7	☐6	☐5	☐4	☐3	☐2	☐1
75. Ich würde das Produkt gegen kein anderes eintauschen	☐7	☐6	☐5	☐4	☐3	☐2	☐1
76. Ich kann es kaum erwarten, das Produkt erneut zu verwenden.	☐7	☐6	☐5	☐4	☐3	☐2	☐1
77. Im Vergleich zu diesem Produkt wirken andere Produkte unvollkommen.	☐7	☐6	☐5	☐4	☐3	☐2	☐1
79. Ich würde mir genau dieses Produkt jederzeit (wieder) zulegen.	☐7	☐6	☐5	☐4	☐3	☐2	☐1
80. Wenn ich mit dem Produkt zu tun habe, vergesse ich schon mal die Zeit.	☐7	☐6	☐5	☐4	☐3	☐2	☐1

Wie erleben Sie das Produkt insgesamt?
(Mit einem X die Stelle auf der Skala markieren)

VICINO LUZERN
EII4Life
i Home Lab HOCHSCHULE LUZERN

Was gefällt Ihnen gut am Produkt?

Was sollte am Produkt verändert/verbessert werden?

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7.2 Annex 2: Informed Consent

Project title: Ella4Life		
Principal Investigators:		
Background: Ella4Life is a virtual assistant and fun to use. It's an integration of a mobile system, and a speech controlled system used in people's homes. She supports people in different stages of vitality in life: vital people in need of guidance and support in embracing a healthy lifestyle; chronically ill people in need of guidance and support in embracing a healthy lifestyle; chronically ill people in handling their chronic deceases; and people with cognitive and/or physical problems by making it easy for them to handle a digital support system. In doing so, Ella4Life offers people one solution for care and cure. The Ella4Life project requires pilot study phases. During these phases, more than 300 voluntary participants will be recruited in four different European States (The Netherlands, Poland, Rumania, and Switzerland). Participants will be introduced to the correct use of Anne and Emma and then they will be invited to use the system for an agreed period of time. During this period the volunteers will be interviewed by researchers. The interview will last approximately 30 minutes and researchers may take note or tape/videotape the interaction between the system and the users. Privacy and confidentiality will be always guarantee during the pilot study.		
Participant Declaration:		
I have read or have had the information about the project and I understand the contents.	Yes	No
I have been given an opportunity to ask questions and am satisfied with answers.	Yes	No
I consent to take part in the study.	Yes	No
I understand that participation is voluntary and that I can withdraw at any time.	Yes	No
I understand that withdrawal will not affect my access to services or legal rights.	Yes	No
I consent to possible publication of results.	Yes	No
I consent to the use of images, video and sound recordings containing personal data.	Yes	No

I consent to the use of my vital data, such as blood pressure.	Yes	No
I give my permission to: Use the data obtained from you in other future studies without the need for additional consent.	Yes	No
Researcher Declaration:		
I have explained the study to the participant.	Yes	No
I have answered questions put to me by the participant about the research.	Yes	No
I believe that the participant understands and is freely giving consent.	Yes	No
I guarantee the protection of natural persons with regard to the processing of personal data and on the free movement of such data according to the Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016.	Yes	No

Participant's Statement:

I have read, or had read to me, this consent form. I have had the opportunity to ask questions and all my questions have been answered to my satisfaction. I freely and voluntarily agree to be part of this research study, though without prejudice to my legal and ethical rights. I understand I may withdraw from the study at any time. I have received a copy of this consent form.

Participant's Name:

Contact Details:

Participant Signature:

Date:

The form needs to be signed by the consenter and dated.

Researcher's Statement: I have explained the nature and purpose of this research study, the procedures to be undertaken and any risks that may be involved. I have offered to answer any questions and fully answered such questions. I believe that the participant understands my explanation and has freely given informed consent.

Signature:

Date: