GUARDIAN

The social robot companion to support homecare nurses

D2.2 Ethics/gender and data protection compliance protocol

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VERSION HISTORY

Version	Authors	Date	Description
0.1	Jessica Rochat (HUG)	20/05/2020	First full draft
0.2	Henk Herman Nap (Vilans)	31/05/2020	Check & review
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0.4	Jessica Rochat (HUG)	20.02.2021	Completion of section 4
1.0	Henk Herman Nap (Vilans)	22.02.2021	Final version

Guardian

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1 Executive summary

This deliverable presents the key elements and regulations to take into account regarding ethics, gender and data protection. The first section describes ethics considerations, the second one presents how to address gender issues and the last one identifies data protection regulations to follow.

Acronyms used in this deliverable	
VIL	Vilans
CCARE	ConnectedCare Services B.V
SRS	Smartrobot.solutions
JEF	JEF S.r.l.
TU/e	Eindhoven University of Technology
UNIGE	University of Geneva
HUG	University hospitals of Geneva
UNIVPM	Università Politecnica della Marche
INCRA	National Institute of Health and Science on Aging
ZNWV	Zorggroep Noordwest-Veluwe

2 Ethics

During the Guardian project, several research methods such as interviews, focus groups, usability test and pilot test will be used to design and test the developed Guardian social robot and platform in the project. To ensure that the rights regarding ethics and data privacy of the participants involved in Guardian co-creation and research activities are respected, each activity must take into account ethical guidelines and human subjects' rights described in this section. Moreover, ethics principles and guidelines are described in depth in the deliverable *D1.3 Ethical and legal manual*.

2.1 AAL Guidelines

The AAL Programme encourages researchers to aim for ethical excellence, and remind, in their AAL Guidelines [1], that it is not a "nice to have" but a "must have" and that research activities must be compliant with ethics regulations and standards. The Guardian project coordinator Vilans participated in the AAL webinar on Friday February 12, 2021, on AAL Guidelines for Ethics, Data privacy and Security. In Guardian, the information and knowledge from the guidelines and webinar are implemented in the project.Following AAL guidelines, the framework for ethics compliance involved four steps. These steps are illustrated in the picture below :

Figure 1: Framework for compliance. Source: AAL Guidelins for Ethics, Data Privacy and Security.

Basic principles

"Fundamental Ethical principles indicate that an intent to do good or provide help must always be the underlying motive for action. However, intent to do good is not sufficient. The potential for good must sufficiently outweigh the potential for harm. This soft law concept includes a series of ethical codes of conduct, texts and principles to guide the protection and respect of the human rights and dignity of human beings, based on 4 principles (beneficence, non-maleficence, autonomy and justice)." Cited from AAL Guidelines for Ethics, Data Privacy and Securtity [1].

EU Regulations

"This area refers to a set of constructed legal directives and regulations to enforce the protection of any endeavor involving human beings (i.e. Convention of Oviedo) or the data privacy and security (i.e. GDPR General Data Protection Regulation). The European Data Protection concern is not new, it is an ongoing reform process continuously adapting and based on 3 main principles:

- to build on the previous Data Protection Directives since 1995 (95/46/EC),
- to increase transparency and accountability of the data processing,
- to enhance the data protection rights of the individuals.

With the emerging digital age – e.g. big data, Internet of Things, automation/robotics, artificial intelligence, machine learning and blockchain – some very relevant legislation for AAL was approved, as the 2018 General Data Protection Regulation No. 679/2016 (GDPR) and the text currently under

discussion: the new EU ePrivacy Regulation, supplementing GDPR for electronic communication of personal data." Cited from AAL Guidelines for Ethics, Data Privacy and Securtity [1].

International Standards

"The European Union has established a system of standards and rules for bringing innovation, services and products safely to the market, in full respect of its citizens' rights and privacy. They directly apply to the functioning and general security measures of the product or service itself, such as the label "CE" or "ISO", but also concern the privacy and security of personal data. There are some relevant standards to be considered for the AAL community:

- ISO TC314 | Ageing Committees - https://www.iso.org/committee/6810883.html
- ISO 82304-2 | Health and wellness apps - https://www.iso.org/standard/78182.html

As for CE marking (https://ec.europa.eu/growth/single-market/ce-marking_en), it applies to specific products, indicating that the manufacturer declares compliance of that product with the relevant European product safety legislation. It is, in principle, a self-certification process. Only for a few products it is required to have the product tested and certified by a Notified Body." Cited from AAL Guidelines for Ethics, Data Privacy and Securtity [1].

National framework and regional regulations

"After ensuring that a product or service is complying with the different international regulations - and eventually adding value to it by conforming to standards or achieving the CE mark -, it is still necessary to ensure that it also obeys to the national or regional regulations of the countries where it will be used or commercialised. For the development phase this usually implies the need to acquire ethical approval for studies; when going to the market it may be required to have specific authorisation from municipalities, regions or national agencies." Cited from AAL Guidelines for Ethics, Data Privacy and Securtity [1].

2.2 Ethical principles

Ethical principles that must be followed during the project are listed and explained in the deliverable *D1.3 Ethical and legal manual*. These principles are drawn from The Norwegian National Research Ethics Committes [2] and describe 14 principles to follow: 1. Guest for truth, 2. Academic freedom, 3. Quality, 4. Voluntary informed consent, 5. Confidentiality, 6. Impartiality, 7. Intergrity, 8. Good reference practice, 9. Collegiality, 10. Institutional responsibility, 11. Availability of results, 12. Social responsibility, 13. Global responsibility, Laws and regulations.

2.3 Rights and ethics

2.3.1 Human and fundamental rights

This section describes the human and fundamental rights of European citizens according to European laws that must be guaranteed for all participants involved in the project.

Right to respect for private and family life, European Convention on Human Rights, article 8 [3]

1. Everyone has the right to respect for his private and family life, his home and his correspondence.
2. There shall be no interference by a public authority with the exercise of this right except such as is in accordance with the law and is necessary in a democratic society in the interests of national security, public safety or the economic well-being of the country, for the prevention of disorder or crime, for the protection of health or morals, or for the protection of the rights and freedoms of others.

Protection of personal data, Charter of Fundamental Rights of the European Union, article 8 [4]

1. Everyone has the right to the protection of personal data concerning him or her.
2. Such data must be processed fairly for specified purposes and on the basis of the consent of the person concerned or some other legitimate basis laid down by law. Everyone has the right of access to data which has been collected concerning him or her, and the right to have it rectified.
3. Compliance with these rules shall be subject to control by an independent authority

2.4 Informed consent

The article 3 of the Charter of fundamental rights of the European union [4], specifies the need for "the free and informed consent of the person concerned, according to the procedures laid down by law". Therefore, for each research being performed in the project, researchers will ensure that each participant receives the necessary information about the research and give its consent. A common template of information sheet and consent form (Annexe 1) were created and shared with all partners. These templates and their content follow the European Commission requirements [5]. The content of the information sheet and the consent form may vary following the type of the research and the different national regulations that may be concerned.

2.5 National laws and ethical committee's approvals

National laws regarding ethics and research were identified for each end-user site and are described in the deliverable *D1.3 Ethical and legal manual*. Each end-user site will follow and respect their respective national laws.

2.5.1 The Netherlands

The national laws that will be respected in the Netherlands are the following:

- The Netherlands Code of Conduct for Scientific Practice, 2014 [6]
- Code of conduct for research and statistics (Gedragscode voor Onderzoek en Statistiek, 2010) [7]
- Handleiding voor verwerkers van persoonsgegevens: Wet bescherming persoonsgegevens (2002). (Manual for processors of personal data: Data Protection Act) [8]
- Handleiding voor de toetsing van medisch-wetenschappelijk onderzoek met mensen (2002). (Manual for the review of medical research involving human subjects) [9]
- CCMO-Notitie gedragswetenschappelijk onderzoek en de WMO: enkele conclusies. (Note behavioral scientific research and WMO: a number of conclusions.). December 2001. [10]
- Privacy bij wetenschappelijk onderzoek en statistiek. Kader voor gedragscode. Hooghiemstra, 2002. (Privacy in scientific research and statistics.) [11]
- Nederlandse Gedragscode Wetenschapsbeoefening (Dutch Academic Integrity VSNU) [12]
- Gedragscode voor gebruik van persoonsgegevens in wetenschappelijk onderzoek VSNU: (Code of conduct for use of personal data in research) [13]

2.5.2 Italy

The national laws that will be respected in Italy are the following:

- Guidelines for Research Integrity [16]
- Informed Consent in Scientific Research:Ethical Toolkit [15]
- Ethical Charter on Social Sciences and Humanities Research [16]
- General authorization to process personal data for scientific research purposes, 2012 [17]

2.5.3 Switzerland

The national laws that will be respected in Switzerland are the following:

- Human Research Law [18]
- Ordinance on Human Research with the Exception of Clinical Trials [19]

2.5.4 Ethics committee approval

Each end-user sites will be responsible to verify if an Ethical Committee (EC) approval is required for each research activity that involves end-users. If an activity requires the approval of a national Ethics Committee [20][21][22] (e.g., if medical data has to be shared with third parties), the local partner will have to submit the protocol to the EC and receive approval. In case of doubt, whether an ethical approval or not is needed, each trial site will be encourage to check with their Ethical Committee and/or ask for an exemption from ethical approval process.

For the co-creation and design phases in the Netherlands, ethical approval will be asked for via the ethical committee of Eindhoven University of Technology. For the Alpha & Beta study, we will submit the research protocols to the regional Medical Ethical Technical Committee (METC) of the province of Noord-Brabant, region Arnhem-Nijmegen or the Independent Review Board Nijmegen (depending on where most of the participants will be recruited) [23].

In Italy, for Alpha and Beta tests, the research protocols will be submitted to INRCA Ethical Committee in Ancona.

In Switzerland, for Alpha and Beta tests, the research protocols will be submitted to the Cantonal Research Ethics Committee in Geneva.

3 Requirements for privacy and data protection

Regardind data protection, the following national and European laws in force will be respected among the Guardian project:

- Wet Bescherming Persoonsgegevens (WBP) [24]
- General Data Protection Regulation (GDPR, Regulation (EU) 2016/679) [25]
- Federal Act on Data Protection (Switzerland, 2019) [26]

As stated in the deliverable *D1.3 Ethical and legal manual*, "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."

3.1 Protocol for collecting, storing and sharing data

This protocol aims to define how personal data will be collected, stored and shared, to make sure that EU regulations are followed and that data are collected and handled in a correct manner. The following guidelines will have to be followed by each partners:

- All the collected data and the results will be anonymized
- Information that contains personal data should be kept confidential, encrypted and not shared outside the group in charge for collecting the data
- Data will be stored on a secure location in line with EU and national regulations
- Data can only be shared among partners in the project with written consent of the participants involved
- Each end-user partner will act as the "controller" of the data they are collecting, according to the EU and national regulations
- The GUARDIAN eco-system must guarantee full confidentiality for personal information at all stages of the R&D process

4 Gender, sex and minorities

This section describes the importance of considering gender, sex and minorities in research. Its aim is to raise awareness of this issue among the project's partners and to define guidelines to follow. Among the Guardian project, partners will be encouraged to follow Responsible Research & Innovation (RRI) guidelines regarding gender issues [27]. More precisely, Guardian project will follow the advices described in the *Toolkit for Gender in EU-funded research* [28].

4.1 Gender in research

For the European Commission, when applying strategies to promote gender in research, three advices should be taken into account :

1. "Women's participation in science and research must be encouraged;
2. Research must address women's needs as well as men's;
3. There should be research on the gender question itself, to enhance understanding of gender issues in science and research." [28]

Concretely, to respect gender in research, specific actions should be performed by all project partners, as described below.

4.1.1 Women's participation in research

To encourage women's participation in research it's then necessary to involve female researchers in working teams and at all levels. It is well known that all around the world, the women gender is less prevalent in the higher positions of the academic field. To cope with gender inequality in the research field, a stronger effort should be place when recruiting [28].

Guardian partners then engage to encourage equal participation of men and women workers in the research teams.

4.1.2 Gender, sex and minorities dimensions of research

Gender in research is also concerned when addressing the gender dimension of research. Gender should be considered as an entire variable, by assessing the potential gender issues and consequences in the specific research field.

Some gender-specific issues could emerged and should be identified, specifically in health research and healthy ageing. Indeed, studies show that one factor of health inequality and disparities is the gender inequality [29]. Several gender disparities have been identified such as the risk for senior women to be more prone to poverty and isolation [30] and a shorter life expectancy for women [31] due to a higher exposition of chronic illness, cardiovascular disease and mental illnesses [32][33].

Studies show that it is important to consider the different gender, sexes, but also minorities, to ensure quality and generalizability of the results as they may have differences in cultural influences and biological variables [34].

The national institute of health of the United States of America, emphasizes the need to understand how sex and gender may influence the research questions and the research findings [35]. They formulate several advices to guide researchers:

1. Perform a literature review to assess if and how the sex and gender dimensions may affect the research question
2. Take into account the sex of the participants when analyzing the results
3. Report if sex has an influence, or not, on the results

To consider minorities in research, such as transgender and gender nonconforming people but also lesbian, gay and bisexual people, guidelines have been developed by the American Psychological Association to guide researchers [36][37]. If some participants being part of the minorities category are involved in the Guardian project, researchers will be advised to read these two guidelines cited above. These guidelines will help to understand the specificities of these minorities, to know if and how some specific attitudes should be adopted and if some research questions should be further investigated.

To summarize, gender, sex and minorities dimensions can have an influence on health outcome, our findings and can create health disparities. Among the Guardian project, gender and sex variables will be taken into account to explain how the developed solutions meet both men and women needs or expectancies, that may be different. The gender variable could also explain potential differences on the use of the Guardian solution and variables outcomes that are related to health or well-being such as the quality of life for example. Among Guardian project, a specific effort will then be made during the recruitment to involve an equitable number of men and women participants.

5 References

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6 Annexes

6.1 Annexe 1: Information sheet and consent form template in English

GUARDIAN project

"Information sheet"

Title of the project: GUARDIAN
Financing: European Commission & [NAME OF THE NATIONAL CONTACT ORGANIZATION]
Coordinator: Vilans, The Netherlands
Duration: 2020-2023

The AAL project GUARDIAN is focused on improving the lifestyle of frail seniors and their caregivers considering the extreme impact of this disease in the world. Lifestyle monitoring can reduce caregiver's distress and thereby extend the period that the informal caregiver can sustain the care and support needs for the person with dementia with affective return in terms of patient life quality and social costs.

The project is funded in Call X of…. The international consortium working on this project consists of 10 partners from the following countries: The Netherlands, Italy, and Switzerland.

USER INVOLVEMENT

Despite technology offering many options, people have different reasons to doubt its use. To dispel these doubts and let the solution align with real practics, systems and services must be developed in line with the needs of potential users and stakeholders. With this in perspective, different user sessions are organized with formal and informal carers, and people with dementia, including various interested groups in order to gather information about their wants and requirements of the GUARDIAN services. All the results will be used to identify the 'users' needs' and to define the services and system specifications.

This [STUDY / EVALUATION] is aimed at gaining knowledge about:

[MENTION THE KNOWLEDGE THAT IS PLANNED TO BE GAINED]

GUARDIAN project

"Informed Consent"

Dear sir/madam,

You are kindly invited to take part in the [user session / evaluation] described below. This activity is part of the European research project GUARDIAN. Before you agree on participating, it is important to read carefully this consent form and understand the procedure. If you have any questions or remarks, do not hesitate to let us know.

1. AIM OF THE PROJECT

The aim of the GUARDIAN project is to develop social robotics – including an GUARDIAN platform/app – for formal and informal carers, and frail seniors. GUARDIAN is intended to provide context relevant information, reminders and advise by means of the GUARDIAN robot, based on activity data gathered by the robot.

2. GOAL OF THE [EVALUATION / USER SESSION]

The purpose of this [evaluation / session] is to better understand [the needs, wishes and preferences of the users] regarding the GUARDIAN system. XYZ

3. PROCEDURE

In the [XYZ]…

4. VOLUNTARY PARTICIPATION

No experience with assistive technology is required. You are asked to participate in this [evaluation / session] on a voluntary basis. You can withdraw at any point in time without explanation.

5. RISKS

No risks to expect.

6. ADVANTAGES

Your personal experience and opinion are valuable input. This information is the basis for further R&D activities in the field of independent living and assistive technologies.

7. ANONIMITY AND PRIVACY

Directly identifying information is removed from the data and replaced by a code, in order to guarantee anonymous data analysis and representation. Confidential data will be stored in a safe or locked file cabinet, and handled only by authorized staff members.

Information from the user session will be used for internal reports. Some outcomes might be used for GUARDIAN dissemination and Journal or Conference publications as well.

8. CONTACT DETAILS

For more information about your rights as participant, for further questions or in case you are unsatisfied about the way the user session is executed, you are free to contact the following researchers:.

- [Name – organisation – email@email.com]
  Responsible for execution of user session in [country].
- Henk Herman Nap – Vilans – h.nap@vilans.nl and Dirk Lukkien – Vilans –and [XYZ]
  Responsible for the study protocol of the user sessions in GUARDIAN.

9. CONFIRMATION

If you are still interested to participate in the GUARDIAN [evaluation / user session], please check the boxes below, and confirm your participation with your full name, date and signature on the bottom of the page.

1	I have carefully read this document. I had the opportunity to ask for clarification, and I confirm that I understand all the information.	☐
2	Based on the information, I agree to participate voluntarily in the user session.	☐
3	I agree on making audio recordings.	☐
4	I agree on making photographs.	☐
5	My data can be used for the above described communication and research purposes.	☐

This Informed Consent applies to all three sessions that are organized as part of the [evaluation / co-creation – phase 1]. For each session we ask for your signature.

☐ Session 1	☐ Session 2	☐ Session 3
Date:	Date:	Date:
_____	_____	_____
Signature:	Signature:	Signature:
_____	_____	_____

6.2 Annexe 2: Information sheet and consent form template for Switzerland

Informations destinées aux participants DD.MM.YYYY

Cette étude est organisée dans le cadre du projet européen Guardian, financé par le programme Active Assisted Living (AAL), avec plusieurs partenaires européens: Vilans (Pays-Bas), ConnectedCare (Pays-Bas), smartrobot.solutions (Pays-Bas), Université d'Eidhoven of Technology (Pays-Bas), Universita Politecnica delle Marche (d'Italie), INRCA (d'Italie), JEF (d'Italie), Zorggroep Noordwest-Veluwe (des Pays-Bas), Université de Genève (de la Suisse, y compris le département des sciences de l'information médicale à les Hôpitaux universitaires de Genève (de Suisse).

Projet Guardian : [nom de l'étude]

Madame, Monsieur,

Afin de concevoir les fonctionnalités d'un robot social pour accompagner les soins à domicile qui répondent aux besoins des utilisateurs, les Hôpitaux Universitaires de Genève vous invitent à participer à [nom de l'étude].

Description du projet

Guardian est un projet de recherche européen visant à concevoir et développer un robot social pour soutenir les personnes âgées recevant des soins à domicile dans leur vie quotidienne et permettant d'augmenter leur qualité de vie. Un robot social peut accompagner et accompagner les seniors dans leurs tâches quotidiennes tout en surveillant leur quotidien. Par exemple, le réseau de soins (soignants formels et informels) peut savoir à travers le robot comment se porte la personne âgée. Cela pourrait comprendre la surveillance de l'apport alimentaire, de l'exercice, de la prise de médicaments et des émotions. Cela permet au réseau de soins de mieux comprendre les changements possibles dans le rythme quotidien et de savoir quand des soins supplémentaires pourraient être nécessaires.

Sélection des personnes pouvant participer à l'étude

La participation est ouverte à [critères d'inclusion]

La participation est cependant fermée à [critères d'exclusion]

Description et déroulement de l'étude

Afin de [objectif de l'étude], nous menons [méthode de l'étude], durant les mois de [période de l'étude]. Les données de cette étude sont collectées grâce à [technique pour le recueil des données]. [...] sera enregistré. [Le test] sera guidé par une assistante de recherche et durera environ [durée].

Droits des participants

Vous devez prendre part à cette étude uniquement selon votre propre volonté. Personne n'est en droit de vous y pousser ou de vous influencer de quelque manière que ce soit. Vous n'aurez pas à justifier votre refus. Si vous choisissez de participer, vous pourrez à tout moment revenir sur cette décision. Là non plus, vous n'aurez pas à justifier votre retrait de l'étude. Vous pouvez à tout moment poser toutes les questions nécessaires au sujet de l'étude. Pour ce faire, vous pouvez vous adresser à l'assistant de recherche qui vous accompagne ou aux personnes indiquées en fin de ce document.

Risques pour les participants

[La participation à cette étude ne comporte aucun risque.] ou [La participation à cette étude comporte les risques suivants : …]

Avantages pour les participants

Votre participation à cette étude permettra de [faire progresser les connaissances sur les besoins des utilisateurs concernant les robots sociaux afin de soutenir les soins à domicile et faciliter le travail des soignants formels, la vie quotidienne des personnes âgées recevant des soins à domicile et des soignants informels]. Pour votre participation à l'étude, vous recevrez une compensation financière de [montant] CHF, qui sera versée par virement bancaire dans les 1 mois après votre participation. Un mail vous sera envoyé pour vous informer de l'exécution du virement bancaire. Dès réception du virement, nous vous demanderons de signer une feuille attestant de la bonne réception de l'indemnité financière et de nous la renvoyer signée (scan ou photo) par mail ou par SMS ou WhatsApp.

Confidentialité et anonymisation des données

Les données seront récoltées de manière confidentielle et les données seront anonymisées. Nous respectons toutes les dispositions légales relatives à la protection des données en vigueur en Suisse. Nous utiliserons vos données uniquement dans le cadre de l'étude. Toutes les personnes impliquées dans le projet sont soumises au secret professionnel.

Consentement et participation

Veuillez lire attentivement le formulaire suivant. N'hésitez pas à poser des questions lorsque vous ne comprenez pas quelque chose ou que vous souhaitez avoir des précisions. Vous êtes libre d'accepter ou de refuser de participer à l'étude. Si vous décidez de participer, vous pourrez à tout moment revenir sur votre décision et vous retirer de l'étude. Vous n'avez pas à justifier votre décision.

Nous sommes à votre disposition pour toute information complémentaire concernant la participation à cette étude. Vous pouvez à tout moment poser toutes vos questions et demander toutes les précisions nécessaires aux responsables de l'étude.

Guardian

Fiche de consentement pour les participants

Projet Guardian : [nom de l'étude]

La personne soussignée :

- Déclare avoir été informé(e), par le chercheur de l'étude soussigné, oralement et par écrit, des objectifs et du déroulement de l'étude ainsi que des effets présumés, des avantages, des inconvénients possibles et des risques éventuels ;
- Affirme avoir reçu des réponses satisfaisantes aux questions posées en relation avec ma participation à l'étude. Je conserve la feuille d'information datée du DD.MM.YYYY et reçois une copie de ma déclaration de consentement écrite. J'accepte le contenu de la feuille d'information qui m'a été remise sur l'étude précitée ;
- Prend part à cette étude de façon volontaire. Je peux, à tout moment et sans avoir à me justifier, révoquer mon consentement à participer à l'étude,
- Affirme avoir lu attentivement et compris les informations écrites fournies, informations à propos desquelles j'ai pu poser toutes les questions que je souhaitais ;
- Atteste qu'un temps de réflexion suffisant m'a été accordé ;
- Consent à ce que les investigateurs de cette étude travaillent avec les données que je lui-leur ai livré, à condition toutefois que la confidentialité et l'anonymisation de ces données soient strictement assurées.

Signature du participant

Lieu, date	Nom, Prénom	Signature du/de la participant/e

Attestation du chercheur de l'étude

Je certifie par la présente avoir expliqué au participant toutes les informations relatives à l'étude. Je déclare respecter toutes les obligations liées à ce projet conformément à la loi en vigueur. Si je prends connaissance, à tout moment au cours de l'exécution du projet, d'éléments susceptibles d'influencer le consentement du participant à participer à l'étude, je m'engage à l'en informer immédiatement.

Signature du chercheur

Lieu, date	Nom, Prénom	Signature du chercheur

Responsable de l'étude :

Jessica Rochat, BSc, MSc

Responsable de l'équipe Evalab

Service des Sciences de l'Information Médicale

Jessica.rochat@hcuge.ch

Chercheur de l'étude :

[Prénom Nom], BSc, MSc

[Fonction]

Service des Sciences de l'Information Médicale

[Mail]

AAL PROGRAMME

6.3 Annexe 3: Information sheet and consent form template for Italy

Progetto GUARDIAN

"Scheda informativa"

Titolo del progetto: GUARDIAN
Finanziamento: Commissione europea & [INRCA]
Coordinatore: Vilans, Paesi Bassi
Durata:2020-2023

Il progetto AAL GUARDIAN è focalizzato sul miglioramento dello stile di vita degli anziani fragili e dei loro caregiver, considerando l'impatto nel mondo. Il monitoraggio dello stile di vita può ridurre il disagio del caregiver e quindi aumentare il tempo in cui il caregiver informale riesce a sostenere le esigenze di assistenza e supporto per la persona con demenza con ritorno emotivo in termini di qualità della vita del paziente e dei costi sociali.

Il progetto è finanziato nel AAL JP. Il consorzio internazionale che lavora a questo progetto è composto da 10 partner provenienti dai seguenti paesi: Paesi Bassi, Italia e Svizzera.

COINVOLGIMENTO DEGLI UTENTI
Nonostante la tecnologia offra molte opzioni, le persone hanno diversi motivi per dubitare del suo utilizzo. Per dissipare questi dubbi e far sì che la soluzione si allinei con pratiche reali, i sistemi e i servizi devono essere sviluppati in linea con le esigenze dei potenziali utenti e degli stakeholder. In questa prospettiva, vengono organizzate diverse sessioni di valutazione con caregiver formali e informali e persone con demenza, inclusi vari gruppi interessati, al fine di raccogliere informazioni sui loro desideri ed esigenze sui servizi da sviluppare nel progetto GUARDIAN. Tutti i risultati saranno utilizzati per identificare le esigenze degli utenti e per definire i servizi e le specifiche di sistema.

Questo studio ha lo scopo di acquisire conoscenze su:

[MENZIONARE LE CONOSCENZE CHE SI INTENDE ACQUISIRE]

Progetto GUARDIAN

"Consenso informato"

Caro signore/signora,

Sei gentilmente invitato a partecipare alla sessione di valutazione descritta di seguito. Questa attività fa parte del progetto di ricerca europeo GUARDIAN. Prima di acconsentire alla partecipazione, è importante leggere attentamente questo modulo di consenso e comprendere la procedura. Se avrà domande o osservazioni, non esiti a farcelo sapere.

1. OBIETTIVO DEL PROGETTO
L'obiettivo del progetto GUARDIAN è estendere la robotica sociale - inclusa una piattaforma/app GUARDIAN - ai caregiver formali e informali e anziani fragili. GUARDIAN è diretto a fornire informazioni,

promemoria e suggerimenti rilevanti per tale contesto tramite il robot GUARDIAN, sulla base dei dati di attività raccolti dal robot.

2. OBIETTIVO DELLA SESSIONE DI VALUTAZIONE

Lo scopo di questa valutazione è di comprendere meglio [le esigenze, i desideri e le preferenze degli utenti] riguardo al sistema GUARDIAN. XYZ

3. PROCEDURA

In [XYZ]...

4. PARTECIPAZIONE VOLONTARIA

Non è richiesta alcuna esperienza con la tecnologia assistiva. Ti viene chiesto di partecipare a questa valutazione su base volontaria. Puoi ritirarti in qualsiasi momento senza spiegazioni.

5. RISCHI

Non ci si aspetta nessun rischio.

6. VANTAGGI

La vostra esperienza personale e le vostre opinioni sono contributi importanti. Queste informazioni costituiscono la base per ulteriori attività di ricerca e sviluppo nel campo del vivere autonomamente e della tecnologia assistiva.

7. ANONIMATO E RISERVATEZZA

Le informazioni direttamente identificative vengono rimosse dai dati e sostituite da un codice, al fine di garantire l'analisi e la rappresentazione anonime dei dati. I dati riservati saranno conservati in un armadietto sicuro e bloccato e utilizzati soltanto dai membri autorizzati del personale.
Le informazioni della valutazione saranno utilizzate per i report interni. Alcuni risultati potrebbero essere utilizzati anche per la divulgazione del progetto GUARDIAN e per pubblicazioni su riviste o conferenze.

8. INFORMAZIONI DI CONTATTO

Per maggiori informazioni sui tuoi diritti di partecipante, per ulteriori domande o nel caso in cui tu non sia soddisfatto del modo in cui viene eseguita la sessione utente, puoi liberamente contattare i seguenti ricercatori: Roberta Bevilacqua, IRCCS INRCA, r.bevilacqua@inrca.it

9. CONFERMA

Se sei ancora interessato a partecipare al progetto GUARDIAN, controlla le caselle sottostanti e conferma la tua partecipazione con nome, data e firma in fondo alla pagina.

1 Ho letto attentamente questo documento. Ho avuto l'opportunità di chiedere chiarimenti e confermo di aver compreso tutte le informazioni.

2 Sulla base delle informazioni, acconsento a partecipare volontariamente alla sessione utente.

3 Acconsento alla registrazione audio.

4 Acconsento al fare fotografie.

5 I miei dati potranno essere utilizzati per le finalità di comunicazione e ricerca sopra descritte.

Il presente consenso informato si applica a tutte e tre le sessioni organizzate nell'ambito delle attività previste per il co-design. Per ogni sessione è richiesta la vostra firma.

Sessione 1	Sessione 2	Sessione 3
Data:	Data:	Data:
_____	_____	_____
Firma:	Firma:	Firma:
_____	_____	_____

6.4 Annexe 4: Information sheet and consent form template for Netherlands

Informatieblad voor deelnemers November 2020

GUARDIAN-project

Dit onderzoek wordt georganiseerd in het kader van het Europese project GUARDIAN, dat wordt gefinancierd door het Active Assisted Living (AAL)-programma. Bij dit project zijn verschillende Europese partners betrokken: Vilans (Nederland), ConnectedCare (Nederland), smartrobot.solutions (Nederland), Technische Universiteit Eindhoven (Nederland), Universita Politecnica delle Marche (Italië), INRCA (Italië), JEF (Italië), Zorggroep Noordwest-Veluwe (Nederland), Universiteit van Genève (Zwitserland) en de afdeling medische informatiewetenschappen van de Universitaire Ziekenhuizen van Genève (Zwitserland).

Co-creatie met eindgebruikers

De GUARDIAN sociale robot zal worden ontworpen om senioren te helpen langer zelfstandig thuis te blijven. Tegelijkertijd kan dit de werklast van informele en formele zorgverleners verminderen. We zullen een gebruikersgerichte en waardegerichte co-design benadering hanteren waarbij eindgebruikers (gebruikers- en kopers) zijn betrokken om hun behoeften te leren kennen en om de individuele componenten van het systeem en het systeem als geheel stapsgewijs te ontwikkelen en te testen.

Als zodanig is uw bijdrage en deelname zeer essentieel en wordt dit gewaardeerd omdat het helpt om de 'gebruikersbehoeften' te identificeren en de services en systeemspecificaties te definiëren. Door uw ervaringen en meningen te delen, kunt u ons helpen te begrijpen hoe de GUARDIAN sociale robot senioren en hun formele en informele zorgverleners in het echte leven zou kunnen helpen. Hoe meer we hierover leren, hoe beter we in staat zijn om een robot te ontwikkelen die mensen ten goede komt die dergelijke ondersteuning nodig hebben.

Toestemmingsformulier voor deelnemers

Geachte heer mevrouw,

Om een sociale robots ter ondersteuning van thuiszorg te ontwerpen die aan de behoeften van gebruikers voldoet, nodigt ConnectedCare & ZNWV u uit om deel te nemen aan een interview om de behoeften van gebruikers op te halen.

1 Doel van de studie

Guardian is een internationaal onderzoeksproject dat werkt aan het ontwerp en de ontwikkeling van een sociale robot die senioren die thuiszorg ontvangen in hun dagelijks leven kan ondersteunen en hun levenskwaliteit kan verhogen. Een sociale robot kan gezelschap bieden en de senioren ondersteunen bij taken in hun dagelijkse leven. Zo kan het zorgnetwerk (formele en informele zorgverleners) via de robot in de gaten houden hoe het met de senior gaat. Dit omvat het monitoren van voedselinname, lichaamsbeweging, medicatie-inname en emoties. Dit geeft het zorgnetwerk inzicht in mogelijke veranderingen in het dagelijkse patroon en zodoende weet men beter wanneer extra zorg nodig kan zijn.

2 Selectie van deelnemers die kunnen deelnemen aan de studie

Deelname staat open voor:

1) senioren van 65 jaar of ouder die in Nederland of grensoverschrijdend wonen en thuiszorg ontvangen

2) formele zorgverleners die thuiszorg bieden en in Nederland wonen of dichtbij de grens met Nederland, met minstens één jaar ervaring en die minstens 18 jaar oud zijn.

3) Mantelzorgers die familieleden zijn van een senior die thuiszorg ontvangt, in Nederland wonen of grensoverschrijdende werknemers, die hem ondersteunen in zijn leven en minstens 18 jaar oud zijn.

Alle deelnemers moeten een goede schriftelijke en mondelinge begrip van de Nederlandse taal hebben.

3 Beschrijving van het onderzoek

Om een eerste concept van Guardian te evalueren, voeren we interviews met eindgebruikers in de maand november 2020. De gegevens voor dit onderzoek worden verzameld via online interviews via Microsoft Teams die worden opgenomen om de gegevens achteraf gemakkelijker te bewerken. Het interview wordt begeleid door een onderzoeksassistent en duurt ongeveer 1 uur.

4 Rechten van deelnemers

Deelnemen aan deze studie is uit vrije wil. Niemand heeft het recht om je te dwingen of je op welke manier dan ook te beïnvloeden. U hoeft uw weigering van deelname niet te rechtvaardigen. Als u ervoor kiest om deel te nemen, kunt u deze beslissing op elk moment intrekken. Ook dan hoef u uw terugtrekking uit het onderzoek niet te rechtvaardigen. U kunt op elk moment vragen stellen over de studie. Neem hiervoor contact op met de personen aan het einde van het toestemmingsformulier.

5 Risico's voor deelnemers

Er zijn geen risico's verbonden aan deelname aan dit onderzoek.

6 Voordelen voor de deelnemers

Uw deelname aan dit onderzoek zal de kennis over de behoeften van gebruikers met betrekking tot sociale robots in de thuiszorg vergroten.

7 Vertrouwelijkheid en anonimisering van gegevens

De gegevens worden vertrouwelijk verzameld en de gegevens worden geanonimiseerd door identificerende informatie met een code te verwijderen. We voldoen aan alle wettelijke voorschriften met betrekking tot gegevensbescherming die van kracht zijn in Nederland. We zullen uw gegevens alleen gebruiken voor de doeleinden van de studie. Alle bij het project betrokken personen zijn onderworpen aan het beroepsgeheim.

Informatie uit de gebruikerssessies wordt gebruikt voor interne rapportages. Sommige resultaten kunnen ook worden gebruikt voor de verspreiding van resultaten van het GUARDIAN project en in publicaties van tijdschriften of conferenties.

8 Toestemming en deelname

Lees het volgende formulier zorgvuldig door. Stel gerust vragen als je iets niet begrijpt of opheldering wenst. Het staat u vrij om aan het onderzoek deel te nemen of te weigeren. Als u besluit deel te nemen, kunt u uw beslissing op elk moment terugdraaien en u terugtrekken uit de studie. U hoeft uw

beslissingen niet te rechtvaardigen. We staan tot uw beschikking voor verdere informatie over deelname aan dit onderzoek. U kunt op elk moment al uw vragen stellen en alle nodige details opvragen bij de verantwoordelijken voor het onderzoek.

Bevestiging van deelname

Als u bereid bent om deel te nemen aan de GUARDIAN-interviewsessie, vink dan de onderstaande vakjes aan en bevestig uw deelname met uw volledige naam, datum en handtekening onderaan de pagina.

1. Ik heb dit document zorgvuldig gelezen. Ik heb de gelegenheid gehad om opheldering te vragen en ik bevestig dat ik alle informatie begrijp.

2. Op basis van de informatie stem ik ermee in om vrijwillig deel te nemen aan de gebruikerssessie.

3. Ik weet dat ik kan besluiten om niet deel te nemen. Ik weet ook dat ik het interview op elk moment kan stoppen, zonder dat ik hoef uit te leggen waarom. Ik begrijp dat het voor mij of iemand anders geen vervelende gevolgen heeft.

4. Ik begrijp dat ik altijd kan besluiten om sommige vragen niet te beantwoorden, zelfs als ik dit toestemmingsformulier heb ondertekend.

5. Mijn antwoorden kunnen worden vastgelegd en de gegevens kunnen worden gebruikt voor de hierboven beschreven communicatie- en onderzoeksdoeleinden.

Dit toestemmingsformulier is van toepassing op interviews die worden georganiseerd als onderdeel van de gebruikersbehoeftenanalyse van GUARDIAN. Voor elk interview vragen we apart om uw handtekening.

Naam:

Plaats:

Datum:

Handtekening:

Ondergetekende deelnemer:

- verklaart mondeling en schriftelijk te zijn ingelicht over de doelstellingen en het verloop van het onderzoek, alsmede over de vermoedelijke effecten, voordelen, mogelijke nadelen en mogelijke risico's;

- bevestigt een bevredigend antwoord te hebben ontvangen op de vragen die zijn gesteld in verband met deelname aan het onderzoek. De deelnemer bewaart het informatieblad en ontvangt een kopie van zijn of haar schriftelijke toestemmingsverklaring. De deelnemer accepteert de inhoud van het onderzoek dat in het bovenstaande informatieblad is gegeven;

- Neemt op vrijwillige basis deel aan dit onderzoek. De deelnemer kan op elk moment en zonder zichzelf te hoeven rechtvaardigen, zijn of haar toestemming voor deelname aan het onderzoek intrekken;

- bevestigt dat hij of zij de verstrekte schriftelijke informatie zorgvuldig heeft gelezen en begrepen, en eventuele vragen kon stellen;

- bevestigt dat er voldoende tijd is gegeven om na te denken over deelname;

- geeft toestemming aan de onderzoekers van dit onderzoek om te werken met de gegevens die de deelnemer hen verstrekt, op voorwaarde dat de vertrouwelijkheid en anonimisering van deze gegevens strikt is gewaarborgd.

Handtekening deelnemer

Plaats, datum	Voornaam + achternaam	Handtekening deelnemer

Verklaring van de onderzoeker

Ik verklaar hierbij dat ik de deelnemer alle informatie met betrekking tot het onderzoek heb gegeven. Ik verklaar dat ik alle verplichtingen met betrekking tot dit project nakom in overeenstemming met de geldende wetten. Als ik op enig moment tijdens de uitvoering van het project kennis krijg van elementen die de instemming van de deelnemer om deel te nemen aan het onderzoek kunnen beïnvloeden, dan breng ik de deelnemer hiervan op de hoogte.

Handtekening van de onderzoeker

Plaats, datum	Voornaam + achternaam	Handtekening onderzoeker

Contactgegevens

Neem voor meer informatie of bij vragen a.u.b. contact op met onderstaande onderzoekers:

Onderzoeker 1:	Onderzoeker 2 & 3 :
Dirk Lukkien	Judith de Koning & Minke ter Stal
Senior onderzoeker eHealth	E-health designer & Onderzoeker
Vilans	ConnectedCare & Vilans
[email]	[email]