Deliverable 1.5

Ethical Guide and Data Protection Plan

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Abstract

The purpose of D 1.5 is to define the ethical and legal issues related to working with human voluntary end users within the Ella4Life project. It will refer to two distinct categories: issues related to the implementation of the project and issues related to the solutions adopted in the project. Both must apply the national and international ethical rules specific for end-users and to society in general, from the concept phase to test installations and eventually launching in the market.

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3.0	M36	The final document	Cosmina Paul, Mircea Marzan, Magdalena Velciu	Ana Aslan International Foundation

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Executive Summary

An important activity within WP1 (Management) is the development of the recommendations meant to support that all partners respect the ethical guidelines and data protection.

This document discusses relevant ethical aspects related to Ella4Life project. It has been a live document which has driven lab and test fields and it has been created by Ana Aslan International Foundation (henceforth ANA) having the partners as active contributors.

The reason for which the Consortium paid attention to ethical aspects is tow-folded: Ella4Life is a new integrative solution and so the ethics of prototype are of concern from the very start of the project. More, the project has been conceptualized from the onset as a patient-centred research project which aims at advancing new technology in the life of elderly citizens in order to prolong their independence at home. Therefore, ethics of data is also of relevance here.

This document is designed under the ethical excellence philosophy for all the pilot countries: Switzerland, Romania, Poland and Netherlands. It guarantees the compliance to AAL ethical principles, while it ensures the compliance to the national legislations and regulations of the countries involved.

The first chapter presents the relevance of this document, its structure and its relationship to other deliverables.

The second chapter discusses the partners' ethical commitment as it has been assumed by the Consortium and each partner. The Work organization is presented, along the principles and responsibilities followed, and, more, the support offered by the Ethics Committees of Ana Aslan International Foundation (Romania) and Virtask BV (Netherlands).

Key international and national documents, which has been referred here, are presented. The fourth chapter discusses the data protection and the officers' data protection are presented as well as the guidelines.

Ethics of the prototype, data and practices are of concern for the following sections. Ethics od device in the E4L testing contexts and relevant information is offered by the technical partners. The ethics of data is duly presented. Both ethics of device and ethics of data lay the ground for the ethical commitment in the ethics of practice.

1. Introduction and scope

D1.5 Ethical Guide and Data Protection Plan is part of WP 1. Management. The aim is to ensure that all partners respect the ethical guidelines, legal issues and data protection and security related to working with older adults voluntary (end users) within the Ella4Life project. These must be compliant to national and international principles, regulations, standards, frameworks and the aim for **ethical excellence** as it is outlined by AAL Guidelines (2020).

The document helps the researchers involved to identify and address ethical dimensions, while involved in E4L project, financed by the EU Framework. This document is used together with other guidance documents, either provided by the European Commission or by national institutions.

1.1. Why it is important?

This document is important because it helps partners to integrate their research ethics in this project and research.

The Solution proposed within this project raise ethics concerns which are inherent to any new technologies developed and to the fact that vulnerable people are involved, i.e. older adults. Hence, it is important to guarantee safe conditions for research participation for people who may benefit from research, but also for researchers themselves.

COMPLIANCE TO AAL MODEL FOR EXCELLENCE

We are determined to follow the AAL Model for Excellence:" to do the right thing, at the right time, in the right way" and AAL principles: justice, equality of access, and respect for autonomy and dignity.

The Ella4Life solution has to respond to the highest ethical, legal and privacy/data management standards and demands, from the perspective of protecting the older adults' users and assuring the feasibility of the proposed solution, in all stages from creation to adoption.

CHALLENGES

As we have designed The Ella4Life integrative solution for older users and people in vulnerable situations, we faced two challenges: a) protecting older adults as beneficiaries of the Ella4Life solution, facing physical, mental and functional increasing impairment and b) concerns and risks arising from using new technology that is often unfamiliar to the end-users.

COMPLIANCE TO THE EUROPEAN CHARTER FOR RESEARCHERS

The researchers involved in the project enjoy respect for academic freedom as it is stipulated in the Article 13 of the Charter of Fundamental Rights of the European Union (2000), which is legally binding on EU member states. However, they are

responsible towards the following which may play as limitations towards their academic freedom.

- the older adult participants in the research from Netherlands, Romania, Poland and Switzerland and their rights, safety, well-being and interests (or dignity, integrity, rights, and autonomy) need to be recognized and respected,
- older adults' communities which have been identified in all the 4 countries, that are engaged and involved in the research; and
- society at large, in terms of the impact that the Solution may have, but also in terms of avoiding potential misuse or unintended consequences of research results.

1.2. The deliverable structure

The deliverable is structured as following:

1. Introduction and the deliverable short presentation
2. Ethical commitment
3. Key International and national Documents
4. Ethics of prototype
5. Ethics of data
6. Ethics of practices
7. References
8. Appendixes

1.3. Relationship to other deliverables/ actions/ stakeholders

We aimed at respecting ethics in all stages of the project, from the conceptualization of the Solution to the involvement of users, in vulnerable situations or not. By employing a participatory design process and field trials, we were obliged to constantly review and pay attention to the ethical dimensions.
Hence, ethics concerns arouse over multiple Deliverables, as it is shown in the table below:

Deliverables	Aim &Scope	Stakeholders
D1.5 Ethical Guide and Data Protection Plan	specific activities and action plan required for securing the adequate management of ethical and data protection related issues	All partners
D2.1 Specification of overall end-user requirements	identify and define the overall requirements of the end-users' part of the iterative testing	End-users and their family, medical doctors, etc end-user partners
D2.2 Specifications for Ella4Life	the overall requirements and interactive techniques (user interfaces, user cases)	Technical partners

D3.2 System Specification and User interface Specification document	description of interfaces to the outside world (and communicate with 3rd party devices and systems)	Technical partners
D4.1 Validation & testing concept	validation and testing procedures to be performed by the end of every development iteration	All partners
D4.2 Report on users involvement & management	specify the target groups and user recruitment process in detail	end-user partners End-users and their family, medical doctors, etc.
D4.3 Trials setup & deployment report	Ella4Life consortium will set up and configure the Ella personal virtual assistant system to be used by the end-users	All partners End-users and their family, medical doctors, etc
D5.1 Dissemination	all dissemination and exploitation activities	All partners

1.4 About Ella4Life and its benefits

Why and for whom?

With help of Ella4Life, elderly people - healthy or with a chronic disease or mental condition - stay healthier and live a more pleasant life, independent and safe. At home and 'on the road'. Ella will support and encourage people to adapt a healthy lifestyle. Users will be more self-supporting and independent of professional healthcare, what will result in cost reduction and effectiveness. Ella will improve the quality of life of users and relieve healthcare professionals and informal caregivers.

What?

Ella4Life is a virtual assistant and fun to use. It's an integration of a mobile system – on the road - 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 (some) support and guidance in embracing a healthy lifestyle; chronically ill people in handling their chronic diseases; and people with cognitive and/or physical problems by making it easy for them to handle a digital support system.

How?

She will – by speech (recognition) - help with daily structure and stimulate people mentally and physically as a 'lifestyle-coach'. She helps people to manage themselves better. She helps to stick with a healthy lifestyle and can share information – for instance when physical or cognitive capabilities are declining - with professional or informal caregivers when necessary and approved by the end user.

Ella4Life is the integration of Emma (Medicine Men), Anne (Virtask) and specially developed sensor technology from the Gdansk University of Technology

(Politechnika Gdanska). The sensor technology will be the e-chair – monitoring your heart whilst sitting on a chair - and e-bath; a bathmat that has built-in sensors that will keep an eye and the bather. These two Polish products are still in the development stage. Emma and Anne are functioning digital assistants for elderly people and people with a chronic disease.

Emma is a mobile solution and has a working connection with several e-health self-management solutions. She stimulates her users to lead an active, less sedentary and healthy life. Besides stimulating self-management, she also connects the user to their informal caregiver and the professionals within several fields of chronic diseases. This connection makes it possible to monitor the disease and act and instruct when needed and not when planned.

Anne is an avatar that supports - by speech and screen - elderly people with their daily life. By reminding them (of appointments, take their medication, drink some water etc.), activating them and structuring their day. She reads the news, makes video-calling very simple, entertains - via games, radio, personal pictures and video's - and can be connected to home automation. Via telemetry she can notice changes in behaviour.

Integration of Anne, Emma and the sensor technology in Ella4Life will result in an integral solution.

Benefits for the individuals

E4L has promoted a more active and safe life for the older adults who have participated in the testing. When testing Ella, the aim was to prevent falling, accidents and any risks which may occur in the home environment of the older adults, while when testing Anne, a more active ageing has been encouraged, while also trying to prolong independence and fight social isolation, for a more general increase in the well-being and quality of life of the older adults. In short, Ella and Anne looked to increase end-users' physical activity, strength, balance, coordination and to reduce the risk of falling and improve independence, well-being and the quality of life.

Indirectly, an improvement in life quality of family members and caregivers also occurred. If Ella is based mostly on the prevention of adverse falls and their consequences, Anne is also on supporting and motivating elderly towards healthier and more active lifestyles which will allow them to fully experience their advanced ageing and retirement years, maintaining their independence and full control of their lives.

Benefits for the society

Ella: Any intervention aiming to prevent the occurrence of older adults' accidents at home may also result in a reduction of the direct costs related to the medical services and also the indirect costs related to other health and care pathway, such as psychological consequences.

Anne. Any intervention aiming to encourage and support the maintenance of cognitive functions and to prevent cognitive deterioration, as long as maintaining an independent life and, moreover, any action which encourage an active life and fight against older adults' social isolation may also result in a reduction of the direct costs related to the medical services and also the indirect costs related to other health and care pathway, such as depression, memory loss and others as such.

2. E4L Partners' Ethical Commitment

All partners confirmed that they respected the the ethical principles. In so doing, they have been duly supported by ANA, the partners and/or by their own ethical commitees.

2.1. Introductory remarks

This section presents the proposed solution Ella4Life, the ethical standards to which our work has been aligned to, and the ethical commitment of the partners.

We have drawn from the general principles of the international and national laws, directions, and legal documents that are key documents for the Ella4Life partners.

The Ella4Life partners were recommended to review and study the documents prior to arranging research activities and engaging with potential senior users.

We have also listed below the related ethical committees and organizations that can provide further assistance in conducting ethically sound research.

The Ella4Life partners' commitment is coordinated by ANA. That means that on the one hand, each partner is responsible for ethical and legal concerns while, on the other hand, ANA provides support to the partners for complying with the highest ethical commitment.

This arrangement has been set due to the relevance of ethical concern in our research work and to the responsibilities we carry towards our partners in AAL projects.

2.2. Work Organization

Over our work, members with experience in ethical standards have been employed. For giving advice on ethical matters and issues especially in the aspects of the dignity, autonomy and values (human and professional) of the primary and secondary end users.

ANA's experts and the internal and external experts in data protection and ethics have been involved during the project. Given the structure of the Consortium, members have the necessary qualifications and expertise to examine and evaluate the ethical, scientific, methodological, and medical aspects of the proposed studies.

It is the responsibility of each of the partners to evaluate studies and trials for which an application is made. In particular, the subject of evaluation are activities with connotations of research and trials.

ANA's tasks is to monitor trials' progresses by examining the existing documentation pertaining to subjects of the study, verifying the validity of the request from a programmatic, scientific and methodological point of view, confidentiality, information to the patient and consent, adherence to the national and international regulations.

ANA may maintain direct contact with ongoing testing activities, monitoring their performance and the adherence to standards. Researchers may not begin testing until such authorization has been received and will communicate the trial's start date.

Furthermore, the Ethics Committee observes the ethical issues concerning the relationship between all end user groups and the project, including informal carers.

The E4L ethics committee was responsible for:

- ✓ Evaluation and approval of inclusion and exclusion criteria

  Given the aim and the scope of the project, general and inclusive criteria have been decided and older adults with subjective cognitive impairment have been included, as they are fully aware and to offer the informed consent.

- ✓ Supervision of the recruitment process of participants

  Each country of the four involved presented and discussed in the bi-monthly meetings various aspects concerned with the recruitment process. Over the pandemic, online recruitment process in Poland and Romania, and the prolongation of previous field trials in Switzerland did not pose any risk related to the ethics in the supervision process.

- ✓ Support of developing the informed consent document
- ✓ Evaluation and approval of rules for privacy and data protection
- ✓ Evaluation of potential risks and analysis of safety issues related to Emma testing
- ✓ Approval of all documents containing ethical issues
- ✓ Supervision and support of the approval by the national ethical committees especially defining the time frame for writing and submitting to the relevant authorities at the national level

All these tasks have been completed with the support of the following persons:

Luiza Spiru – Ana Aslan International Foundation. Prof. Luiza Spiru, MD, PhD, Professor of Geriatrics, Gerontology and Old Age Psychiatry since

2013, Chair of the Department within "Carol Davila" University of Medicine in Pharmacy in Bucharest since 2004. Luiza is also the Head of the University Department of Geriatrics within "Elias" University Emergency Clinic Hospital since 2003 and the President of the Ana Aslan International Foundation (AAIF; https://anaaslanacademy.ro/), established in 2000 in Bucharest – an NGO dedicated to create, develop and deliver state-of-the-art education & research programs and medical services in the field of brain aging.

Mr. Roge Müller. He reports to the Rector and periodically to the Executive Board. Edith Birrer is responsible for implementation in the E4L project.

Angelique Wolf for LiveLife.

During this project and for questions regarding ethical issues, implementation and coordination **Ms. Annemarie Johannes**, is responsible. She is assisted by the project manager Mrs. Patty-Lou Middel-Leenheer.

2.3. Partners' Own Ethics committees

The partners own ethics committees are an informal way of supporting the ethical activities within the Consortium. Their advice, support and tools offered are relevant due to the experience and outstanding expertise in issues related to ethics, legal aspects and data protection.

Ethics Committee of the Ana Aslan International Foundation:

Ana Aslan has its own Ethics Committee. An internal ethical review board overview the project's full adherence to the important ethical aspects. The internal commission was constituted by Decision no. 122 / 26.05.2020 and has internal competencies, regarding the activity of FAAI. Some ethical issues have been discussed and approved by the committee.

The internal ethical board has the following members:

President: MD. Ana Maria Doscan, Geriatric and Gerontology

Members: Cosmina Niculescu, Geriatric and Gerontology Specialist

Florina Coman, Administrative Director

Ana Bontea provides legal advice, though she does not take part in the Commission.

Hence, since 2020, issues with an ethical content have been circulated and discussed when the case, in order to receive the approval of the ethical review board of E4L.

The Ethics Committee of the Lucerne University of Applied Sciences and Arts:

For the Lucerne University of Applied Sciences and Arts, compliance with data protection is an institutional duty under cantonal law and is the responsibility of the university management and the university's organizational units. The departments are responsible for the implementation of and compliance with data protection in their departments. The Ethics Committee of the Lucerne University of Applied Sciences and Arts assesses the ethical justifiability of research projects at the Lucerne University of Applied Sciences and Arts, insofar as an ethical assessment of the research projects and publications is requested by third parties or the researchers.

The Ethics Committee is chaired by Prof. Dr. Orlando Budelacci. The E4L project is carried out at the Department of "Technology & Architecture" at the Lucerne University of Applied Sciences and Arts. Prof. Dr. Viktor Sigrist is the responsible committee member for this department. During the project and for questions regarding its implementation, the E4L project manager Clemens Nieke is responsible.

2.4. Values and ethical commitment related to the project

If our commitment towards ethical excellence has been transnational and strictly followed EU legislation, we have also made specific efforts to align with the national legislation which can have different provisions. We also need to account that Switzerland is the country which is involved in E4L project, but it is not a member of the European Economic Area (EEA).

In Ella4Life project, ethical commitment is two folded: the involvement of the older adults, and the ethics which revolve around ICT and innovation are of concern.

a) With respect to developing user requirements, focus-groups have been implemented. End user organizations were in charge of bringing the end users into the requirements process, and the questions asked (see D2.1 User Requirements) did not concern private issues or any other issues which may raise ethical concerns.

b) Pilot implementation. End user organizations are involved in the preparation, procedures, and organization of the end user trials, the selection and interviews of trial participants and the continuous evaluation of the end user perception and valuation. In the following more talk on the ethical concerns involved in piloting will be presented.

c) Designing the solution. Furthermore, the directly and indirectly, involved actors respectively users of data and information, as well as their aims and wills, have to be considered.

Finally, a regulatory and ethics compliance monitoring of each Pilot execution was taking place during the whole project life-cycle.

Further, they guarantee the application of **proper privacy and ethics procedures** during the whole project with special precautions for particularly

people at risk, with cognitive or physical impairments. The consortium, therefore, 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*. Also, the directives issued for ICT developments by the *UN International Action Plan on Ageing* will be followed strictly.

Integrity, Health, Safety, and Accessibility of the person: safety protocols and procedures will be defined and used during user participation with the aim of preserving **users' security**.

Providing the Ella4Life solution both mobile and in their homes to help older adults managing their daily activities can only work if **the aims and wills of the people** concerned are taken into account carefully.

The provided solution should be prepared to support people but not to incapacitate them. Distributive **justice and fairness** in the access to the provided services should be considered throughout pilot implementations and commercial launch.

In this context, it is worth noting some key ethical principles and tension areas that seems to govern both research and practice in this area:

- Autonomy and consent of the end-user;
- Benefice to end-user – balancing risk tolerance and risk aversion – safety, confidence and independence;
- Achieving a balance between prevention, avoiding harm and respecting decisions, dignity, integrity and preferences;
- Justice – treating the individual fairly and respecting its rights.

3. Key International and National Documents

3.1. International Documents

In pursuing E4L aim, we are committed to the highest standards and good practices. If we were looking to comply to the legal standards and fundamental rights, we were equally committed to the excellence in ethics as it was promoted by AAL guideline.

Relevant reports and information have been consulted and analysed in order to assess their relevance for the current project. By taking this large analysis in scope we have made the efforts to align with the standards and legislation for human subject research.

The following documents were scrutinized in order to decide their relevance for the E4L project ethical commitment:

- **The Helsinki Declaration** (WMA Declaration of Helsinki – Ethical principles for medical research involving human subjects, 2018) was of relevance to the present research in order to better understand the delineation between

medical research and the research that we have conducted. The E4L is not a medical device per se, and therefore, we do not fall under the regulation of medical research.

- **The CIOMS Guidelines** (Van Delden, Revised CIOMS international ethical guidelines for health-related research involving humans, 2017),
- **European Data Protection** guideline (Regulation 2016/679 of the European Parliament and of the council of 27 April 2016, on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC - General Data Protection Regulation), and the related legislation of the participating partners' Member States.
- **Charter of Fundamental Rights of the European Union** introducing general ethical principles as fundamental rights in Europe, such as protection of human dignity and human life, protection of personal data and privacy as well as the environment; and in accordance with community law and international as well as national conventions. Furthermore, national ethics boards will be consulted, if the case. **Article 13** of the Charter of Fundamental Rights of the European Union (2000);
- COMMISSION RECOMMENDATION of 11 March 2005 on the European Charter for Researchers and on a Code of Conduct for the Recruitment of Researchers (Text with EEA relevance) (2005/251/EC): https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2005:075:0067:0077:EN:PDF;
- **AAL Guidelines for Ethics, Data Privacy and Security (2020)**

3.2. Polish laws

ACT of August 29, 1997, on the Protection of Personal Data

Article 1 1. Any person has a right to have his/her personal data protected.

The processing of personal data can be carried out in the public interest, the interest of the data subject, or the interest of any third party, within the scope and subject to the procedure provided for by the Act. Article 23 Paragraph 1.

The processing of data is permitted only if: the data subject has given his/her consent, unless the processing consists in erasure of personal data and the processing is necessary for the purpose of the legitimate interests pursued by the controllers or data recipients, provided that the processing does not violate the rights and freedoms of the data subject. Paragraph 2. The consent may also be applied to future data processing, on the condition that the purpose of the processing remains unchanged.

Article 24 Paragraph 1. In case where personal data are collected from the data subject, the controller is obliged to provide a data subject from whom the data are collected with the following information:

(1) the address of its seat and its full name, and in case the controller is a natural person about the address of his/her residence and his/her full name,

(2) the purpose of data collection, and, in particular, about the data recipients or categories of recipients, if known at the date of collecting,

(3) the existence of the data subject's right of access to his/her data and the right to rectify these data,

(4) whether the replies to the questions are obligatory or voluntary, and in case of existence of the obligation about its legal basis.

Article 26 Paragraph 1. The controller performing the processing of data should protect the interests of data subjects with due care, and in particular to ensure that:

(1) the data are processed lawfully,

(2) the data are collected for specified and legitimate purposes and no further processed in a way incompatible with the intended purposes, subject to the provisions of paragraph 2 below,

(3) the data are relevant and adequate to the purposes for which they are processed,

(4) the data are kept in a form which permits identification of the data subjects no longer than it is necessary for the purposes for which they are processed.

Article 47. Transfer of Personal Data to a Third Country Paragraph 1. The transfer of personal data to a third country may take place only, if the country of destination ensures at least the same level of personal data protection in its territory as that in force in the territory of Poland.

Paragraph 3. Nevertheless, the controller may transfer the personal data to a third country provided that:

(1) the data subject has given his/her written consent,

(2) the transfer is necessary for the performance of a contract between the data subject and the controller or takes place in response to the data subject's request,

(3) the transfer is necessary for the performance of a contract concluded in the interests of the data subject between the controller and another subject.

3.3. The Netherlands laws

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

- The Medical Research Involving Human Subjects Act (Wet medisch-wetenschappelijk onderzoek met mensen (WMO)) http://wetten.overheid.nl/BWBR0009408/geldigheidsdatum_24-01-2014
- 'The Netherlands Code of Conduct for Scientific Practice', from the Association of Universities in the Netherlands. http://www.vsnu.nl/files/documenten/Domeinen/Onderzoek/The_Netherlands_Code_of_Cond uct_for_Scientific_Practice_2012.pdf Above mentioned act and code are both based on the Helsinki Declaration drafted by de World Medical Association.

These regulations are not fully applicable to E4L, as it is not a medical research.

But the principles of the WMO and the Code can be applied. The most important principles are: 1. Scrupulousness 2. Reliability 3. Verifiability 4. Impartiality 5. Independence

Derived from these principles the most important applicable points are first and foremost the interest and well-being of the participants, their voluntary participation and the possibility to withdraw from E4L at any time.

Legislation concerning data protection **The Dutch "Law Protection of Personal Details"** (http://wetten.overheid.nl/BWBR0011468/geldigheidsdatum_24-01-2014), which is the Dutch implementation of the European Directive 95/46/EC, defines rules and procedures how organisations have to deal with personal details.

The Dutch institute College Bescherming Persoonsgegevens (CBP) is the data protection agency that sees to it that rules are obeyed by organisations and companies. The law defines who is allowed to have access to which data and for which purpose in line with the principles set by the directive: transparency, legitimate purpose and proportionality. People are offered certain rights over data held about them such as the right to know what is held about him and the right to have errors corrected.

This means that collection and processing of data must meet the conditions defined by law and that the older adults in E4L, or his/her legal representative, can exercise some level of control over the information.

The target group of E4L consists of "big group of healthy elderly or with light physical or subjective cognitive impairment", which does not expand the scope of E4L towards healthcare.

3.4. Switzerland laws

In Switzerland, the data protection law is mainly governed by the **Federal Act on Data Protection (DSG) of 1992**. In addition, further data protection statutes are also found at individual canton levels.

The application of EU Data Protection Directive is limited to the territory of the EU states and of the EEA states, (Norway, Iceland and Lichtenstein). In general, each

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

3.5. Romanian laws

GDPR

The general legal framework for data protection has changed substantially since the General Data Protection Regulation (Regulation EU 2016/679 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC) took effect on May 2018.

Despite the GDPR's direct applicability in all EU Member States (including in Romania), the regulation recognises Member States' rights to adopt derogations or additional safeguards in specific cases or with respect to certain types of processing.

In order to regulate such derogations, the Parliament of Romania adopted Law No. 190/2018 Implementing the General Data Protection Regulation (Regulation (EU) 2016/679) ('the Law'), published in the Official Gazette No. 651 of 26 July 2018. The Law regulates special rules for the processing of certain categories of personal data, derogations from the GDPR, provisions regarding data protection officers ('DPO') and certification bodies, as well as provisions on the applicable sanctions for public and private entities.

The provisions relevant in the context of Ella4Life project:

Regulation EU 2016/679 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC - General Data Protection Regulation

Article 6 – Lawfulness of processing;

Article 9 – Processing of special categories of personal data;

Article 23 – Restrictions.

Law no. 190/2018 on implementing measures to Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free

movement of such data and repealing Directive 95/46/EC (General Data Protection Regulation)

Special rules on the processing of certain categories of personal data

Article 3: Processing of genetic data, of biometric data and of health data

(1) The processing of genetic data, of biometric data or of health data for the purpose of automated decision-making or profiling is permitted with the explicit consent of the data subject or if the processing is carried out under explicit legal provisions, with appropriate measures protecting the rights, freedoms and legitimate interests of the data subject. (2) The processing of health data for the purpose of ensuring public health, as defined in Regulation (EC) no. 1338/2008 of the European Parliament and of the Council of 16 December 2008 on Community statistics on public health and health and safety at work, published in the Official Journal of EU, series L, no. 354/70 of 31st of December 2008, cannot be subsequently performed for other purposes by third entities".

Derogations:

Article 8: Processing of personal data for archiving purposes in the public interest, scientific or historical research purposes or statistical purposes (1) The provisions of Articles 15, 16, 18 and 21 of the General Data Protection Regulation do not apply if personal data are processed for scientific or historical research purposes insofar as the rights referred to in those articles are such as to render impossible or to seriously affect the achievement of the specific goals, and the respective derogations are necessary for the achievement of these purposes.

(2) The provisions of Articles 15, 16, 18, 19, 20 and 21 of the General Data Protection Regulation do not apply if personal data are processed for archiving purposes in the public interest, insofar as the rights referred to therein are of a nature to make it impossible or seriously affect the achievement of specific goals, and these derogations are necessary to achieve these goals. (3) The derogations provided for in paragraphs (1) and (2) shall be applicable only subject to the existence of adequate safeguards for the rights and freedoms of the data subjects referred to in Article 89 (1) of the General Data Protection Regulation. (4) Where the processing referred to in paragraphs (1) and (2) serves at the same time for another purpose, the exemptions only apply to the processing for the purposes referred to in those paragraphs.

Article 9 (1) In order to ensure the proportionality and a balance between the right to protection of personal data and special data and the processing of such data by political parties and organisations of citizens belonging to national minorities, to non-governmental organizations, the following guarantees shall be achieved:

a) informing the data subject about the processing of personal data;

b) ensuring the transparency of the information, communications and ways of exercising the rights of the data subject;

c) ensuring the right to rectification and erasure.

In Romania, the GDPR has been implemented by The National Authority for the Supervision of Personal Data Processing (Autoritatea Naţională de Supraveghere a Prelucrării Datelor cu Caracter Personal). It is an autonomous central public authority that acts as the guarantor of compliance and observance of the fundamental rights to protection of personal data and private life.

Ethics

The norms of good conduct in the scientific activity.

In the LAW no. 206 from 27 May 2004 regarding the good conduct in scientific research, technological development and innovation are regulated the good conduct in scientific research and the deviations from the rules of good conduct. All these norms are complemented by the Code of Ethics, provided by Law no. 319/2003 regarding the Statute of Research and Development Staff.

Institutional Ethics Committees (IECs):

According to the Law No. 206/2004, Art. 9 (1) related to the good conduct of scientific research, development, technology and innovation, there are also Institutional Ethics Committees who are established in those institutions who are part of the national system of research and innovation and other units who are providing the validation of the results (e.g. universities or hospitals). Their role is the fulfilling of the specific codes and the resolution of various complaints received. They have an independent body status with a consultative role regarding the safeguarding of the rights, safety and the comfort of the participants in the clinical trials.

3.6. Guidelines for Ethical User Involvement in the Covid-19 context

The E4L second trials took place in the Covid-19 pandemic. Therefore, initial planning had to be adjusted: special measures and procedures for field trials were adapted in order to protect the older adults involved in the trails. Furthermore, specific protective measures and norms should be considered.

The recruitment and adjusting trials (methods):

- We envisioned a recruitment plan to reach our target sample, in pandemic times. Also, we were focused on involving people who offer valuable feedback. In several instances we resorted to online mock up-testing and surveys. Under these conditions, we emphasized the importance of preventing measures and we limited the interaction between numerous people, when we did have person to person interaction, we strongly upheld the rules of hygiene practice to avoid the spread of disease.
- Schedule and flexible time arrangements were made for social distancing and limiting the spread of disease. We accustomed the pilots such as: for

reducing the number of persons invited per session (for face-to-face tests) so we invited just a few people and formed individual groups of 1 - 2 persons only, once a day. Also, we limited their movement and went to see people at their homes. The major risk of contamination will be overcome by moving activities to the online environment and phone calling as it is possible.

Across countries, qualitative data from open questions and telephone follow-ups were collected and quantitative data through standardized questions were taken.

Participants willing to be part in the pilots, received information about how we carried out research, how they could contact our responsible persons and when and how the evaluation is done. Also, it was made clear they were free to leave if they felt like it without the need of giving an explanation. Participation is on a voluntary basis.

The strongest point of Ella4Life system is that it could be used during pandemic times, in social isolation and its benefits increase older adults' sense of security.

4. Data Protection

4.1. Data Protection Officers

It is the responsibility of each of the partner to apply the *Regulation 2016/679 of the European Parliament and of the council of 27 April 2016, on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC - General Data Protection Regulation* and the national data protection legislation.

Each partner in the Consortium has a Data Protection Officer (DPO).

Ms Florina Coman is the data protection officer for ANA.

Ms. Angelique Wolf is the data protection officer for Livelife, Netherlands.

Mr Roge Müller is the Data Protection officer for Lucerne University, Switzerland.

For Virtask BV, compliance with data protection is an institutional duty under Dutch law and is the responsibility of company management. Compliance with data protection and implementation are monitored by both management as well as department heads. A data protection officer has been mandated to support operational issues. This is Mr Gibby Koldenhof, head of IT. He reports to the General Manager and is also part of the Executive Board. Annemarie Johannes is responsible for implementation in the E4L project.

4.2. Data protection guidelines

Data protection and privacy are priorities for the Ella4Life system and services. Therefore, the Ella4Life consortium commits to respecting the principles of

lawfulness, transparency, and fairness laid down in the GDPR and to full compliance with it.

In the framework of the processing of personal data, 'consent of the data subject', Article 4(11) of the General Data Protection Regulation (EU) 2016/679, defined as

> "*any freely given, specific, informed and unambiguous indication of the data subject's wishes by which he or she, by a statement or by a clear affirmative action, signifies agreement to*
> *the processing of personal data relating to him or her".*

The GDPR emphases the requirement that any form of consent have to be informed. Article 5 of the GDPR refers to the requirement for transparency. That is one of the fundamental principles, interplayed with fairness and lawfulness principles. They stress that prior to obtaining subjects' consent, it is important that they take informed decisions, fully agree, understand and consent and are able to fully exercise their right to withdraw their consent. All the accessible information has to be offered, otherwise, the consent will be on invalid basis and the person who is responsible will be in breach of Article 6 of the GDPR.

Data processing, protection and management will be thoroughly described and presented to data subjects in the **Information letter** and **Privacy Policy** prior to participating in the field trials.

Several principles, approaches and measures will ensure compliance with ethical principles and the GDPR. Namely they are:

1. **Explicit consent –** Processing of personal data will be done only after acquiring a signed explicit consent from primary users of the system.
2. **Right of withdrawal –** Throughout the whole Ella4Life project activities, it will be explained and made clear to participants that they have the right to withdraw their voluntary participation and their personal data at any time without giving reasons. Right of withdrawal is included in the *Information Letter, Explicit consent form and the Privacy Policy.* In addition to this, the Ella4Life investigators may *choose to discontinue a participant from the study* at any time if one of the following issues occur:
    - Participant has missed consecutive days of device usage.
    - Ineligibility arising either during the study or having been overlooked at screening and recruitment of volunteers.
    - Participant has suffered acute neurological impairment e.g. a stroke or loss of vision.
    - Significant protocol deviation.
3. **Pseudonymisation -** When personal data is collected offline by Project Partner researchers/ research assistants, pseudonymisation will be used. Article 4(5) of the GDPR describes pseudonymisation as the processing of personal data in such a way that the personal data *cannot be attributed to a specific data subject unless additional information is used.* Such additional information must be kept separately. Simply put, this means that identity of data subjects is concealed

by replacing their real names with codes. For example, Ro – PEU – 01 will be the code used for the first primary end user who will test the Ella4Life prototype in Romania.

Data processors must adopt appropriate technical and organisational measures ensuring that the personal data cannot be attributed to an identified or identifiable data subject. The following security measures will be adopted by the four end user organisations:

- Direct data identifiers will be kept separate from the data set – Name, surname and age of voluntary participants will be included only in the consent form and the socio-demographic survey. All other questionnaires and surveys will have a code. The key to the codes will be known and held only by authorised members of the research teams in the four pilot sites. The key to the codes will be kept locked in a safe in the headquarters of the end user organisations. By separating the direct data identifiers from the data set, pseudonymisation lowers the risk of potential data breach and safeguards personal data.
- Questionnaires/ surveys filled out by project participants will be only identifiable by a code.
- All data that is included in internal reports, tables, internal communications, and external publications such as article/ paper publications or public deliverables will be anonymized and will not contain identifiable details.
- Access to pseudonymised data will be given only to authorised research assistants/ researchers at the four pilot sites.

4. ***Purpose specification –*** Data subjects will be informed about the purposes for the collection and processing of their personal data in the Privacy Policy and the explicit consent.
5. ***Data minimisation*** – Only the minimum amount of data required for the project's purposes will be collected.
6. ***Protection of data*** – Technological measures will ensure protection of personal data when it is collected, stored and transmitted. Firewalls, encoding, encryption and authentication, network security, controlled access will be employed to ensure protection of collected data. Where possible the data will be stored in a locked server. All identification data will be stored separately. For further details on security see **Chapter II, *Section 8. Security enforcement within the project.***
7. ***Designation of Data Protection Officers*** – Under the GDPR, it is mandatory for certain controllers and processors to designate a Data Protection Officer (hereafter called DPO). DPOs perform an important function in personal data protection. Their main duty is to monitor compliance with the GDPR. DPOs act as intermediaries between stakeholders e.g. supervisory authorities, units within an organisation, data subjects etc. DPOs are not personally responsible in case of non-compliance with the GDPR. According to Article 38 the DPO *'is*

involved, properly and in a timely manner, in all issues which relate to the protection of personal data'. They also act as a contact point for the supervisory authority and data subjects.

DPOs have been designated in all organisations part of the Ella4Life consortium. In compliance with Article 37(7) of the GDPR, partners have informed and provided contact details of their DPOs to their national supervisory authority. Their contact details are included in the Privacy Policy for the system. That is, the Ella4Life consortium ensured that data subjects and the supervisory authorities can directly and easily get in touch with their DPOs if such need arises. In addition, a single point of contact for the GDPR at the consortium level has been designated.

8. ***Privacy Policy –*** In general, privacy policy or privacy notice is a public document from an organisation/ company that explains how that organisation/company processes personal information and how it applies data protection principles. Privacy policy must be written 'in a concise, transparent, intelligible and easily accessible form, using clear and plain language, in particular for any information addressed specifically to a child. The information shall be provided in writing, or by other means, including, where appropriate, by electronic means.' Cf. Article 12 (1).

Articles 12, 13 and 14 of the GDPR describe what information must be given to data subjects prior to processing their personal data. In particular, a privacy policy must contain the following:

1) Identity and contact details of the controller;
2) Contact details of the DPO;
3) Purposes of the processing;
4) Legal basis for the processing;
5) Categories of personal data that are collected;
6) Recipients of the personal data if any;
7) Period for which the personal data will be stored;
8) Data subjects' rights;
9) Informing data subjects of their right to withdraw consent at any time, without affecting the lawfulness of processing based on consent before its withdrawal.

5. Ethical aspects related to the prototype testing

5.1. Introductory remarks. Ethical Issues Related to ICT and innovation

Ella4Life consortium puts considerable importance on ethical and privacy issues. The proposed solution to be developed will support autonomy and dignity with

respect to the end-users and quality of life. The aim is to develop the product in close cooperation with the end-users.

The "human-centred-design-approach" indicate that the product is developed for the users benefits and older users must be involved in the technological research process from design to field testing.

In this section, security and privacy issues are analysed, from the perspective of technology ethics. It involves the techniques and tools, as well as the domains and the components that the architecture and design of ELLA4Life solution has taken into consideration. We have to consider the whole picture: technology, the context, the user.

a) Security. The security requirements refer to:

- ✓ Authentication, the method with the user is uniquely identified, and its identity verified.
- ✓ Integrity, the method that ensures that every system, resource, file and information in general can be modified only by authorized entities.
- ✓ Confidentiality, the method by which access to the content of information is available only to authorized users.
- ✓ Non-repudiation, the method that produces cryptographic data that ensure that an entity cannot repudiate its actions.
- ✓ Availability, the method that ensures that a system can fulfil its purpose with a given degree of success.

The Ella4Life solution will preserve the security demands by using the specific security mechanisms for technology. Security mechanisms will also interact with security services to send and receive information.

b) Privacy

Privacy in massively inter-connected environments and its social acceptance from end-users require special attention. These must adopt responsible interfaces, considering multiple requirements (i.e. anonymity, pseudonymity, link-ability / unlink-ability) and data protection regulations in place, enabling:

- ✓ End-users to administrate and control their identities on their own, and
- ✓ Organizations to harmonize their authentication / authorization procedures, to effectively secure and manage their actions.

c) Disclaimer Information

The disclaimer will inform and explain the aim and the way that the gathered information is processed. One of the measures that will be implemented, in order to be in accordance with the recommendation of GDPR, is related to the use of Disclaimers for the use of cookies.

The common aspects in these cases are to do the right thing for all categories of users. The proposed solution should guarantee the end-user autonomy and consent, safety and independence.

5.2. Ethics of devices in the E4L testing contexts

For the E4L project, IT resources are used for the researchers that are subject to IT Services and are therefore subject to its guidelines.

The users use a dummy account one with no personal name or real email address. Which makes it PSEUDONYMIZED PERSONAL DATA

The Anne-software, by Virtask, runs on microsoft devices, which holds certificates such as NEN7510, ISO 27001 and ISO/IEC27018. The user is the owner of the data and is able to see who can get insight to the data. Virtask is following the rules GDPR and has the data stored with high protection levels.

Within Emma the user is the owner of the data and is able to see who can get insight to the data. We use a 2fa, and have regulation certificates that we are following the rules GDPR and have the data stored with high protection levels! We have an ISO 27001 certificate.

The first challenge for E4L was to ensure that devices and protocols created for sharing the data are technologically robust and scientifically reliable. The argument for the technologically soundness is given by the deliverables concerning the technological standards and characteristics. The argument for the scientifical reliability is given by the scientifically awards received and the scientific articles and international conference participation which prove the commitment and high standards of the team.

E4L is a product which is to be used at home, in a private environment and not in a public one. Hence, **personal privacy** is of great relevance here.

E4L is enabling the collection of data about the user's health and behaviours and the analysis by third parties, which create opportunities for **data sharing** and social categorization. If these types of data can support E4L monitoring at the same time expectations of personal privacy can be violated. That is why during the lab testing and field trials, older adults have been informed with respect to that.

For example, **the sensor system raises the concern of personal privacy**. Similar to many other situations, potential violations of personal privacy is justified on the basis of the 'need' for the technology derived from safety concerns (i.e. older adults are monitored while taking a bath as many falls occurs in such unsafe environments).

Therefore, privacy has been critical here, as personal health and activity record are created as soon as data started to be generated by a device. The way this data is transmitted, curated, labelled, stored, and analysed for the benefit of the user, service provider, and other stakeholders is key to the understanding of ethical commitment and the ethical concerns which are raised.

Therefore, a protocol which retains data with well-defined limitations, scope, and purpose, hence testing, has been created. The role of the user (or data subject) in the control of data generated has been considered on ethical and legal grounds, according to the EU legislations and country specific provisions.

In the case of E4L older adults are using **Anne and Emma system for general well-being and not clinical devices**, which implies that many concerns related with obtrusiveness are to which stigma may be attached are not of relevance here. Older adults' general well-being monitored through Anne is unlikely to carry a negative stigma. Older adults monitoring related to Emma system is carry more obtrusiveness or visibility concerns.

With respect to **Emma system, that does not carry a stigma**, which is usually associated with a clinical device because it is not associated with a specific health problem. Moreover, the Emma sensors minimise obtrusiveness in order to protect the autonomy and sense of identity of the older adults.

The ethical acceptability of the Emma and Anne solutions are not to be questioned as they do not violate the norm that the devised are used only as needed. Therefore, "monitoring for monitoring's sake" or pursuing monitoring as an end in itself are thus, avoided.

6. Ethical aspects regarding Data Management

6.1. Personal Data collection & Information

Provided to the end-users and their relatives will include in language understandable to the participant or the representative:

- A description of the project and its aims.
- A specification of all partners and involved end-user groups.
- The system capabilities, the selection criteria, the evaluation procedure and the expected duration of the subject and their participation.
- A description of any benefits to the subject or to others, which may reasonably be expected from the project, such as independent and more comfortable living.
- A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained. In fact, personal data and information of the persons that will participate in the validation process will be encoded in order to preserve anonymity.
- An explanation of whom to contact for answers to pertinent questions about their rights and privacy issues.

- A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty.
- Informed consent will then be obtained from the participants and any payments, inducements or other benefits, if any and in accordance with national approved normative practice, to be given to the persons concerned, will be specified

Personal Data collection

Within Ella4Life activities, personal data will be collected during focus groups, interviews and pilot testing.

Personal data to be collected:

Socio-demographical data: age, gender, marital status, living status

Preferences for: information means, entertainment

Skills: computer literacy level

Sensitive data: Self evaluated physical health (including subjective cognitive impairment) and level of dependency

6.2. Informed Consent

In the first stage of the project, before starting on the testing, we have agreed on the minimum features to take into account in the design of the consent forms. Bellow, we also present the ways in which the partners have engaged with the ethical principles:

- ✓ The information must be written as simple as possible in order to be **widely understandable by the older adults with different educational backgrounds** as they are the main beneficiaries of the Ella4Life project.
- ✓ The research does not involve users with serious disabilities and, hence, no assent from guardian or tutor (informal carer) is mandatory. **Older adults with subjective cognitive disabilities** are involved while testing Anne and Emma, but none with mild cognitive impairments.
- ✓ **Two signed copies**, one for the main researcher and other for the user, have been used, when the case.
- ✓ **An explicit explanation of the research** accounting the institutions involved, purpose and procedures. In the online testing, in the context of Covid-19 pandemic, all this information has been duly disseminated through our social-media channels. We also accounted here for the webpages of the online senior communities, which have been previously mapped. The

prestige of the partners (universities, research institutions and alike) also supported the trust of the older adults involved in the testing.

An Information sheet will also be created.

The content of the Informed participation and consent form & Information sheet is fourfold as follows:

1. **About the Ella4Life Project**: This Section shortly describes the Ella4Life Project, the purposes of the processing of personal data, and the partners of the consortium.
2. **About the Participant**: This Section aims to collect personal details of the participants, notably for evidential purposes.
3. **Participation & Consent**: This Section aims to collect participants' indications of their wish to participate in the Ell4Life Project and their consents to the processing of their personal data in such context.
4. **Information Sheet (Privacy Policy)**: This Section informs the participants of the collection and processing of their personal data in the context of their participation in the Ella4Life Project.

However, the consent form must contain the affirmation that he/she is allowed to ask any question involving the project.

- ✓ **The opportunity to withdraw from the study without any consequence appears on the consent**. This is crucial for user organizations where there is any kind of membership since it must be clear for users that the withdrawal from the project does not affect their membership or service given by the organization.

  Though, there has been no withdrawal. We suspect that that can be an indication of the interest of the beneficiaries and of the fact that the communication has been very well conducted and that the product answer to the expectations of the seniors involved in the project, to their formal and informal carers as well.

- ✓ The ability to withdraw the authorization of anyone to see their data has also been foreseen.
- ✓ The research meets the legal requirements concerning data protection.
- ✓ This data can be rectified at any moment by the user.
- ✓ The name of the name researcher and his/her contact must be written on the form as an ultimate responsible person for inquiries.
- ✓ Each specific Consent form applied at each of the different site locations complies with the above-mentioned requirements so that a common approach is generated across the sites.

How and when to use the Informed participation and consent form & Information sheet

In the case of offline testing in the context of the Ella4Life Project, there are steps which have to be followed:

1. The Informed participation and consent form & Information sheet must be submitted for review and completion to the participant before commencing any personal data processing activities.

2. If the participant has any questions about the Ella4Life Project or the Informed participation and consent form & Information sheet, the Project Partner must ensure that such questions are adequately addressed before commencing the personal data processing activities.

3. The Project Partner must verify that the participant has completed the Sections "About the Participant" and "Consent".

4. The Project Partner must verify that the participant has ticked all the 'Yes'-boxes of the "Participation & Consent" Section. In case the participant has not ticked 'Yes' for each box, do NOT proceed with the personal data processing activities.

5. The Project Partner must ensure to give the participant a copy of the Informed participation and consent form & Information sheet.

6. The Project Partner must be prepared to provide the participant, upon the latter's request, with a copy of the input provided by the participant.

The Project Partner must keep the Informed participation and consent form & Information sheet duly completed by the participant on file (a scanned copy saved on the ELLA4LIFE repository or another appropriate medium).

8. The Informed participation and consent form & Information sheet should be stored during the entire duration of the processing for which the consent was sought. Afterwards, once the retention is no longer necessary for the purpose for which the consent was sought, the document should be stored in accordance with the retention requirements laid down in the applicable legislation and/or for the establishment, exercise or defence of legal claims.

Whenever a Project Partner wishes to gather input from a participant in **an online context** through a survey in the context of the ELLA4LIFE Project, the following steps must be followed:

1. Only use the EU Survey questionnaire prepared by Project Partners to conduct the survey.
2. If the participant contacts a Project Partner directly with any questions about the ELLA4LIFE Project, the personal data processing activities, or the Informed participation and consent form & Information sheet, the Project Partner must ensure that such questions are adequately addressed.

6.3. Data Storage and Handling Processes

The protection of the privacy of participants is a responsibility of all people involved in research with human participants. Privacy means that the participant can control the access to personal information; he/she decides who has access to the collected data in the future.

The provisions relevant of REGULATION (EU) 2016/679 in the context of Ella4Life project:

- Article 6 – Lawfulness of processing:

”1. Processing shall be lawful only if and to the extent that at least one of the following applies:

(a) the data subject has given consent to the processing of his or her personal data for one or more specific purposes;”

- Article 7- Conditions for consent

”1. Where processing is based on consent, the controller shall be able to demonstrate that the data subject has consented to processing of his or her personal data.

2. If the data subject's consent is given in the context of a written declaration which also concerns other matters, the request for consent shall be presented in a manner which is clearly distinguishable from the other matters, in an intelligible and easily accessible form, using clear and plain language. Any part of such a declaration which constitutes an infringement of this Regulation shall not be binding.

3. The data subject shall have the right to withdraw his or her consent at any time. The withdrawal of consent shall not affect the lawfulness of processing based on consent before its withdrawal. Prior to giving consent, the data subject shall be informed thereof. It shall be as easy to withdraw as to give consent.

4. When assessing whether consent is freely given, utmost account shall be taken of whether, inter alia, the performance of a contract, including the provision of a service, is conditional on consent to the processing of personal data that is not necessary for the performance of that contract”.

- Article 9 – Processing of special categories of personal data:

”1. Processing of personal data revealing racial or ethnic origin, political opinions, religious or philosophical beliefs, or trade union membership, and the processing of genetic data, biometric data for the purpose of uniquely identifying a natural person, data concerning health or data concerning a natural person's sex life or sexual orientation shall be prohibited.

2. Paragraph 1 shall not apply if one of the following applies:

(a) the data subject has given explicit consent to the processing of those personal data for one or more specified purposes, except where Union or Member State law provide that the prohibition referred to in paragraph 1 may not be lifted by the data subject;

(b) processing is necessary for the purposes of carrying out the obligations and exercising specific rights of the controller or of the data subject in the field of employment and social security and social protection law in so far as it is authorised by Union or Member State law or a collective agreement pursuant to Member State law providing for appropriate safeguards for the fundamental rights and the interests of the data subject;

(c) processing is necessary to protect the vital interests of the data subject or of another natural person where the data subject is physically or legally incapable of giving consent;

(d) processing is carried out in the course of its legitimate activities with appropriate safeguards by a foundation, association or any other not-for-profit body with a political, philosophical, religious or trade union aim and on condition that the processing relates solely to

the members or to former members of the body or to persons who have regular contact with it in connection with its purposes and that the personal data are not disclosed outside that body without the consent of the data subjects;

(e) processing relates to personal data which are manifestly made public by the data subject;

(f) processing is necessary for the establishment, exercise or defence of legal claims or whenever courts are acting in their judicial capacity;

(g) processing is necessary for reasons of substantial public interest, on the basis of Union or Member State law which shall be proportionate to the aim pursued, respect the essence of the right to data protection and provide for suitable and specific measures to safeguard the fundamental rights and the interests of the data subject;

(h) processing is necessary for the purposes of preventive or occupational medicine, for the assessment of the working capacity of the employee, medical diagnosis, the provision of health or social care or treatment or the management of health or social care systems and services on the basis of Union or Member State law or pursuant to contract with a health professional and subject to the conditions and safeguards referred to in paragraph 3;

(i) processing is necessary for reasons of public interest in the area of public health, such as protecting against serious cross-border threats to health or ensuring high standards of quality and safety of health care and of medicinal products or medical devices, on the basis of Union or Member State law which provides for suitable and specific measures to safeguard the rights and freedoms of the data subject, in particular professional secrecy;

(j) processing is necessary for archiving purposes in the public interest, scientific or historical research purposes or statistical purposes in accordance with Article 89(1) based on Union or Member State law which shall be proportionate to the aim pursued, respect the essence of the right to data protection and provide for suitable and specific measures to safeguard the fundamental rights and the interests of the data subject.

3. Personal data referred to in paragraph 1 may be processed for the purposes referred to in point (h) of paragraph 2 when those data are processed by or under the responsibility of a professional subject to the obligation of professional secrecy under Union or Member State law or rules established by national competent bodies or by another person also subject to an obligation of secrecy under Union or Member State law or rules established by national competent bodies.

4. Member States may maintain or introduce further conditions, including limitations, with regard to the processing of genetic data, biometric data or data concerning health"

- Article 23 – Restrictions:

"1. Union or Member State law to which the data controller or processor is subject may restrict by way of a legislative measure the scope of the obligations and rights provided for in Articles 12 to 22 and Article 34, as well as Article 5 in so far as its provisions correspond to the rights and obligations provided for in Articles 12 to 22, when such a restriction respects the essence of the fundamental rights and freedoms and is a necessary and proportionate measure in a democratic society to safeguard:

(a)national security;

(b)defence;

(c)public security;

(d) the prevention, investigation, detection or prosecution of criminal offences or the execution of criminal penalties, including the safeguarding against and the prevention of threats to public security;

(e) other important objectives of general public interest of the Union or of a Member State, in particular an important economic or financial interest of the Union or of a Member State, including monetary, budgetary and taxation a matters, public health and social security;

(f) the protection of judicial independence and judicial proceedings;

(g) the prevention, investigation, detection and prosecution of breaches of ethics for regulated professions;

(h) a monitoring, inspection or regulatory function connected, even occasionally, to the exercise of official authority in the cases referred to in points (a) to (e) and (g);

(i) the protection of the data subject or the rights and freedoms of others;

(j) the enforcement of civil law claims.

2. In particular, any legislative measure referred to in paragraph 1 shall contain specific provisions at least, where relevant, as to:

(a) the purposes of the processing or categories of processing;

(b) the categories of personal data;

(c) the scope of the restrictions introduced;

(d) the safeguards to prevent abuse or unlawful access or transfer;

(e) the specification of the controller or categories of controllers;

(f) the storage periods and the applicable safeguards taking into account the nature, scope and purposes of the processing or categories of processing;

(g) the risks to the rights and freedoms of data subjects; and

(h) the right of data subjects to be informed about the restriction, unless that may be prejudicial to the purpose of the restriction".
Due to the principle of autonomy the participants have to be asked for their agreement (informed consent) before private information can be collected. It should be also ensured that all the persons involved in research work, understand and respect the requirement for confidentiality. The participants should be informed about the confidentiality policy that is used in the research.

The privacy plays a role at different levels:

Hints to or specific personal information of any participant in publications.

It should be prevented to reveal the identity of participants in research deliberately or

inadvertently, without the expressed permission of the participants.

Dissemination of data among partners.

Access to data method of access, data formats, method of archiving (electronic and

paper), including data handling, data analyses, and research communications. Offer

restricted access to privacy sensitive information within the organization of the partner.

Protection of the privacy within the organization of volunteers (employers, etc.)

throughout the whole process like, communications, data exchange, presentation of

findings, etc.

Destruction of data once the purposes for which the data were obtained (and for

which the consent form was signed) is over.

Workstations will be configured and used in a manner that is consistent with the security practices that will protect data against exposure, but also against tampering and loss of study data sets.

All PCs used for data storage will be password protected. No removable storage media such as CDs or flash memory drives will be used for data storage or transfer.

The investigator is not allowed to circulate information without anonymization. This means that only relevant attributes, i.e. gender, categories of age, etc. are retained. Another possibility is to keep the identity of the participants, but only with prior consent of those.

As already mentioned, protection of confidentiality implies informing the participants about what may be done with their data (i.e. data sharing).

As databases are developed, confidentiality will become increasingly hard to maintain. Simple stripping of the participants name and its replacement with a code is no guarantee of complete confidentiality. Therefor no personal ID data should be collected during any kind of quantitative and qualitative research except for the participants Informed Consent form.

With regard to item (i) and (iii), WP29 notes that in a case where the consent sought is to be relied upon by multiple (joint) controllers or if the data is to be transferred to or processed by other controllers who wish to rely on the original consent, these organisations should all be named. Processors do not need to be named as part of the consent requirements, although to comply with Articles 13 and 14 of the GDPR, controllers will need to provide a full list of recipients or

categories of recipients including processors. To conclude, WP29 notes that depending on the circumstances and context of a case, more information may be needed to allow the data subject to genuinely understand the processing operations at hand.

In order to lawfully obtain the explicit consent of the participant in the ELLA4LIFE Project, an "Informed participation and consent form & Information sheet" was released.

Depending on the purpose for which and the stage at which personal data is collected and processed, there are two versions thereof, namely (i) one in the framework of involvement of the participant in the requirement elicitation for the ELLA4LIFE and (ii) one for the testing and validation of the ELLA4LIFE. The sections underneath, concerning the Informed participation and consent form & Information sheet, however, apply to both versions.

Specific measures:

Computing (PC, workstation, mainframe):

Number of computers on which data will be stored: (all password protected?)

Whether personal computers used in the research project will be attached to a network or will operate independently (stand-alone):

Analysis for data collected from all countries will be analysed from a single standalone computer or from….?

Physical environment in which computer is kept (e.g., in room with public access, in room locked when not in use by research staff):

6.4. Encoding and Anonymization

Information should be anonymized so that individual identities cannot be revealed. Anonymization provides a safeguard against accidental or mischievous release of confidential information.

There are different ways in which personal data can be modified to conceal identities:

- ✓ Coded information contains information, which could readily identify people, but their identity is concealed by coding, the key to which is held by members of the research team using the information.
- ✓ Anonymized data with links to personal information is anonymized to the research team that holds it, but contains coded information, which could be used to identify people. The key to the code might be held by the custodians of a larger research database.
- ✓ Unlinked anonymized data contains nothing that has reasonable potential to be used by anyone to identify individuals.

As a minimum, anonymized data must not contain any of the following, or codes for the following:

- ✓ Name, address, phone/fax. numbers, e-mail address, full postcode.
- ✓ Any identifying reference numbers.
- ✓ Photograph, video or audio files of participants
- ✓ Names of relatives/carers
- ✓ Researcher and database developer should always consider – when designing studies, before passing information to others, and before publishing information- whether data contain combinations of such information that might lead to identification of individuals or very small groups. We will follow the unlinked anonymized data policy, especially since we may include users having identifiers like age, gender and nationality. Once anonymized, the data will not allow tracing back the participant in any way, and any analysis of the data will be based on group analysis.
- ✓ Data will be encoded, and anonymized using numerical codes. During trials and the development stages, the correspondence with the users list will be saved into a local database, which will be encrypted.
- ✓ To avoid accidentally compromising the data, information about the data's sensitivity and any available information on participants' consent should be stored together with the data itself.

Data Destruction

Any personal data gathered from the persons participating in the project are relevant and as minimally as necessary for the successful development of the relevant purposes of the project. However, in this process of data collection, special needs may rise up that require collection of sensitive information when it comes to train or improve a technological device relevant for the project.

Specific measures:

- Dissociation of personal identifiable data as it was specified above.
- Destruction of paper/documents by the time the project ends.
- Erasing of electronic documents containing sensitive information by the time the project
- ends.

Evaluation Criteria of this Data Protection Plan

These data protection plan evaluation criteria will be followed as guidelines throughout the project and its fulfilment will be supervised, deviations from it will be minimized and appropriately justified.

A brief report, describing the fulfilment of these criteria, eventual conflicts, and how these have been solved, will be supervised by AAIF and sent to the Commission at the end of the project.

The proposed criteria that will be observed to measure the fulfilment of this evaluation plan will be the following:

- The users have been informed about the project OBJECTIVES
- The users have given their consent to participate
- What procedures have been in place to preserve the dignity, autonomy and values (human and professional) of the end-users?
- All the data collected in the user requirements questionnaire are necessary (but also are the minimum, in order to avoid asking for non-relevant, but sensitive, information)
- For any data not initially expected or specified in the consent form, a justification for its needs has been reported to the respective ethical committees (if required).

o This may include:

☐ Video information about the users.

☐ Audio information about the users.

- For any data not initially expected or specified in the consent form, additional consent forms have been provided to the users.
- Sociodemographic identification data have been dissociated from the rest of information about the users (except for when it is absolutely necessary for data analysis)
- Sociodemographic identification data have been encrypted on a separate database
- Risk of identifying users in profiles or scenarios have been minimized
- Any file exchanging personal information from the users have been encrypted.
- Scenarios show conflict with legislations about privacy and security
- For those scenarios showing conflict with legislations about privacy and security, necessary adaptations to fulfil these legislations have been carried out.
- Special procedures are planned for safeguarding the right to privacy, self-determination and other ethical issues in of end users related to technology-

enabled concepts for confidential communication between the older person and informal and formal carers, service providers

- Dissemination activities performed do not allow identification of the users.

7. Ethics of practices

- ✓ As it has been showed above, in the Ella4Life project each partner has carefully engaged with specific ethics principles and with their country laws.
- ✓ The online testing which took place during the second trial has strictly followed the ethical engagement related to providing information about the project and having the consent before starting the trial. Based on each specific purpose testing (i.e. sensors, Anne), no identifiable personal and health data have been collected.
- ✓ In the case of Romania and Switzerland, the e-mail addresses have not been collected, while in the case of Poland the respondents have been contacted through the e-mail addresses. For the last case, the respondents have been reassured that the researchers will not attempt to capture information that they do not voluntarily provide. The confidentiality of the e-mail addresses was assured and anonymity was guaranteed as data which is relatable to specific individuals was not collected.

User centred design procedures included in the E4L evaluation, protect user rights from the start of the project until its end,

1) by including usability, ease to learn, acceptability and friendliness of the technologies developed and, also,

2) by including evaluation procedures with the users involved. User-system interaction will be evaluated in order to ensure the most usable system to respond to real user needs, ensuring adequate privacy and safety of the participants.

Users in these phases (first and second prototype) will be recruited from the pool of users of each partner. The processing of the data subjects will be carried out with appropriate safeguards for the rights and freedoms of the participants, including the explanation of the project's procedures and the signature of a consent form. All the ethical aspects involved in the different trials will be explained in detail when the trial scenarios will be developed. For that reason, this deliverable will have additional amendments including the specific ethical issues that will derive from the designed trial scenarios. By now, we can only say that each time the participants carry out a test, evaluation or another kind of participation, they must give their informed consent, which means that the proposed procedure and its implications will be discussed, and only afterwards will the participant sign the relevant form. As explained before, in the informed consent process the following parts are to be discussed:

• Aim of the study. • Voluntary nature. • Risks/ Benefits. • How the information is stored? • How the information is encoded? During the trials, the partners of the project have to share participants' personal and private information. For this reason, they have to follow these principles: • Before starting the trials it is necessary to prepare the users for the situation. That means, to explain the general objective of the evaluation, the methodology to be carried out, and the participation requested of them. Also, all the doubts should be clarified before starting. • During the test, people are not obliged to give details about their own lives • The data will be encrypted or protected with a code during the storage and process Ethical Guide and Data Protection Plan E4L - Anonymized, as the last year, when people came for the audio and video recordings, with the day, number of sessions without names, photographs, identifying numbers. • Each partner should store the information in a secure way. The database will be sealed from people not involved in the project but working in the organization - The correspondence between the numerical codes and the user list will be saved into a local encrypted database. - The data will be stored in a locked server and the identification data will be stored separately. In the same way, it must take into account that after the trial: • It is not allowed to circulate information between partners without anonymization. • Regarding dissemination (paper, publications, conference presentations) it is not allowed: -Listing of individual cases -Description of individual cases -Listing, description or identification of the participants by number, by name, or by descriptive information. The data will be saved for five years after the end of the project. After this time, each partner will be responsible for destroying the personal data in his organization. Whenever a question arises from any partner in the project related with themes about how safeguard.

7.1. Compliance with ethical principles and the GDPR

The European Data Protection concern is 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.

The EU's General Data Protection Regulation (GDPR) applies to personal data processed in electronic form or written records. GDPR Article 4 (1) defines "Personal data" as any information relating to **an identified or identifiable natural person (data subject).**

> An identifiable natural person is one who can be identified, directly or indirectly, in particular by reference to an identifier such as a name, an identification number, location data, an online identifier or to one or more factors specific to the physical, physiological, genetic, mental, economic, cultural or social identity of that natural person. This includes, e.g.: name, surname, home address, e-mail or location data from the map on your mobile.

GDPR is directly applicable in all partners countries. It aims at protecting the people from data collection, processing and data management. That means people have more control over their personal data, while businesses benefit from clear regulations for the market. The protection of personal data of the users and its processing through Ella4Life solution are submitted to the GDPR and fundamental rights in the EU.

GDPR grants the following rights to the data subject: right to information, right of access, right to rectification, right to erasure, right to restriction of processing, right to data portability, right to object.

All partners organizations are aware of the implications of the EU-GDPR for their respective countries. Further, each country has its special legislation rules for the appliance of data protection and privacy.

The Ella4Life system collects ***data concerning health***. According to Article 4 (15) 'data concerning health' means *'personal data related to the physical or mental health of a natural person, including the provision of health care services, which reveal information about his or her health status'*. It is considered ***sensitive personal data*** and it deserves higher protection because the use of such data may have significant adverse effects on data subjects. Therefore, data concerning health is subject to *specific processing conditions* described in Article 9 of the GDPR. Processing of health-related data is prohibited unless some requirements are met. In the case of the Ella4Life, the legal basis for processing this data will be explicit consent given by primary end users as defined in Art.9 (2) (a) and conducting health research Art. 9 (2) (h) and (j). Processing for the purpose of scientific research is defined in Recital 159 of the GDPR as follows:

> *'the processing of personal data for scientific research purposes should be interpreted in a broad manner including for example technological development and demonstration, fundamental research, applied research and privately funded research. [3]In addition, it should take into account the Union's objective under Article 179(1) TFEU of achieving a European Research Area. [4]Scientific research purposes should also include studies conducted in the public interest in the area of public health'.*

The general legal framework for data protection has changed substantially since the General Data Protection Regulation (Regulation EU 2016/679 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC) took effect on May 2018.

Despite the GDPR's direct applicability in all EU Member States (including in Romania), the regulation recognises Member States' rights to adopt derogations or additional safeguards in specific cases or with respect to certain types of processing.

In order to regulate such derogations, the Parliament of Romania adopted Law No. 190/2018 Implementing the General Data Protection Regulation (Regulation (EU) 2016/679) ('the Law'), published in the Official Gazette No. 651 of 26 July 2018. The Law regulates special rules for the processing of certain categories of personal data, derogations from the GDPR, provisions regarding data protection officers ('DPO') and certification bodies, as well as provisions on the applicable sanctions for public and private entities.

The provisions relevant in the context of Ella4Life project:

- **Regulation EU 2016/679** on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC - General Data Protection Regulation
  - **Article 6 – Lawfulness of processing;**
  - **Article 9 – Processing of special categories of personal data;**
  - **Article 23 – Restrictions.**
- **Law no. 190/2018** on implementing measures to Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data and repealing Directive 95/46/EC (General Data Protection Regulation)

Special rules on the processing of certain categories of personal data

Article 3: Processing of genetic data, of biometric data and of health data

(1) The processing of genetic data, of biometric data or of **health data** for the purpose of automated decision-making or profiling is permitted with the explicit consent of the data subject or if the processing is carried out under explicit legal provisions, with appropriate measures protecting the rights, freedoms and legitimate interests of the data subject. (2) The processing of health data for the purpose of ensuring public health, as defined in Regulation (EC) no. 1338/2008 of the European Parliament and of the Council of 16 December 2008 on Community statistics on public health and health and safety at work, published in the Official Journal of EU, series L, no. 354/70 of 31st of December 2008, cannot be subsequently performed for other purposes by third entities".

Derogations

Article 8: Processing of personal data for archiving purposes in the public interest, scientific or historical research purposes or statistical purposes (1) The provisions of Articles 15, 16, 18 and 21 of the General Data Protection Regulation do not apply if personal data are processed for scientific or historical research purposes insofar as the rights referred to in those articles are such as to render impossible or to seriously affect the achievement of the specific goals, and the respective derogations are necessary for the achievement of these purposes.

(2) The provisions of Articles 15, 16, 18, 19, 20 and 21 of the General Data Protection Regulation do not apply if personal data are processed for archiving purposes in the public interest, insofar as the rights referred to therein are of a nature to make it impossible or seriously affect the achievement of specific goals, and these derogations are necessary to achieve these goals. (3) The derogations provided for in paragraphs (1) and (2) shall be applicable only subject to the existence of adequate safeguards for the rights and freedoms of the data subjects referred to in Article 89 (1) of the General Data Protection Regulation. (4) Where the processing referred to in paragraphs (1) and (2) serves at the same time for another purpose, the exemptions only apply to the processing for the purposes referred to in those paragraphs.

Article 9 (1) In order to ensure the proportionality and a balance between the right to protection of personal data and special data and the processing of such data by political parties and organisations of citizens belonging to national minorities, to **non-governmental organizations**, the following guarantees shall be achieved:

a) informing the data subject about the processing of personal data;

b) ensuring the transparency of the information, communications and ways of exercising the rights of the data subject;

c) ensuring the right to rectification and erasure."

Personal Data in Ella4Life project

We collect data from the participants during the different phases (conceptualisation, user requirements, field testing and market entry) in order to gather their feedback on the proposed solution.

The purpose of the data collection will be disclosed to the participants and among other vital information related to the personal data of the participants. Data is **anonymized** and **not traceable**.

However, the personal data of the participants will be secured and their evaluation as well as other information gathered will be **anonymized** and the users cannot be identified according to their responses. In regards to technical implementations for safeguarding the anonymity of the participants, end user organizations are able to register users' feedback without revealing their personal data, as much as possible. Moreover, the personal data already gathered will be stored for 5 years after the project ends, in case of an audit/check/inspection and after that it will be destroyed. All personal data and feedback will also be deleted in case the participant wants to withdraw their participation.

Pilot testing of the Ella4Life system will be performed in Switzerland, Romania, Poland and Netherlands. The results of the study are not planned to be transferred to non-European countries and for that reason all the national regulations related to personal data processing and storage of the above-mentioned countries will be considered

All partners will work with older adults as well as with their informal caregivers in Switzerland, Romania, Poland, and the Netherlands according to high ethical standards. User participation will target those groups of older adults that are legally capacitated and capable of giving **informed consent**.

Every activity undertaken with the users will be fully compliant to the international and European and national privacy and data protection law. Therefore, previous to users participation, the relevant national ethics committee or/and relevant competent authorities will be contacted and informed

Therefore, in all the 4 countries of testing, local anonymisation of data prior to communication helps us to prevent both unauthorised access and identification of the user. However, risks of re-identification of anonymised data through aggregation and re-purposing, and the trade-off between the scientific or commercial value of data and de-identification has been taken seriously and successfully avoided. Privacy risks have been considered.

Switzerland

IT supports the efficiency and effectiveness of business and learning processes and promotes the achievement of the strategic goals of the Lucerne University of Applied Sciences and Arts (business alignment). The Executive Board approves the IT strategy and provides the necessary resources for its implementation. It periodically informs the university council about the status of the use of information technology and about the strategic projects in this area. The Administrative Director issues IT guidelines. "IT Services is responsible for the operational management of IT and submits an IT strategy, including a portfolio of strategic projects, to the University Council. IT Services is the central service provider of IT services and the central service broker for IT services to be purchased from third parties. IT Services has the following tasks in particular:

a.Drafting and implementing the IT strategy,

b.Setting up, operating and maintaining the IT resources, insofar as these are not operated and maintained in a laboratory environment by the users themselves,

c.Maintaining the inventory of the IT resources of the Lucerne University of Applied Sciences and Arts,

d.Running a service desk for the users.

In Switzerland, categories of age and gender have been collected.

Questionnaires completed by end users are not stored within the HSL in their raw form.

In order to make the information from the questionnaires usable for the E4L research project, a pseudonymization is carried out. More detailed information on the questionnaires and "Informed Consent" can be found in the deliverable "D4.1 Validation & Test Concept".

When testing in **Poland,** the users use a dummy account one with no personal name or real email address. Which makes it PSEUDONYMIZED PERSONAL DATA. Within Emma the user is the owner of the data and is able to see who can get insight to the data.

We use a 2fa, and have regulation certificates that we are following the rules GDPR and have the data stored with high protection levels! They have an ISO 27001 certificate.

Partners from Poland did not have to contact any national services since they don't register any data which is relatable to specific individuals.

In the **Netherlands,** the users have been asked to fill in the following information:

- Range of year of birth (for example 1961 - 1970)
- Gender (female/male/other)
- Marital status (married, single, widowed, in a relation)
- With how many people do you live together
- Highest level of education
- General health status (great, good, average, not good, really bad)
- Did you experience any limitation in your daily life due to your physical health.

In Netherlands, data was collected by using a Google Forms. Afterwards, the data was downloaded to a stand alone Windows 10 pro computer including the latest security updates and a 2-factor authentication access.

In Romania, during the second iteration, when testing Anne, the users have been asked to fill in the following information:

- Categories of age (as an ordinal variable, and not collected as ratio data)
- Gender,
- Education,
- Living Arrangement,
- Religion,
- General health state,
- Categories of income (ordinal variable and not collected as ratio data)
- Physical health state,
- Emotional health state

In **Romania,** the GDPR has been implemented by The National Authority for the Supervision of Personal Data Processing (Autoritatea Naţională de Supraveghere a Prelucrării Datelor cu Caracter Personal). It is an autonomous central public authority that acts as the guarantor of compliance and observance of the fundamental rights to protection of personal data and private life.

In Ella4Life project, during the last stage pf testing *Anne, the Virtual Assistance* (2020-2021), 100 persons have been involved. We have involved older users with Subjective Cognitive Impairment based on people self-assessment.

Few testing techniques have been employed in order to gather data in the midst of the pandemic:

Face to face testing

Telephone testing and

Online Testing.

A 4 minutes long movie was made in order to test *Anne concept* and an online questionnaire was conducted. The first part of the movie tells the story of a 70 years old woman, called Cosmina, who lives alone in a big city in Romania, Timisoara. Cosmina used to be a doctor and when she has started to forget easy things, like the steps of a recipe, she realized that her brain had started the degeneration process: and that the broken synapses would lead to forgetfulness. She was aware of the fact that she would need to build up new synapses, to challenge her brain by learning new things, engaging in new activities and exposing herself to new memories and bewilderment in front of the world.

The second part of the movie is about how Cosmina uses Anne, and how Anne suggests new activities, how the medication reminder functions, how the radio and news functions works, the photo album and games. It aims to give an overview on how the app can be used.

Including the end users at risk in the research

When testing Anne, screening for cognitive impairment in those over the age of 65 without symptoms is difficult. Only healthcare professionals and clinicians could assess the person's cognition function e.g. by performing a mental status exam, possibly complemented by the use of neuropsychological testing, including memory tests and possibly tests for other cognitive domains. However, the use of different definitional criteria and different sampling and assessment methods are another cause for which the highly varies.

In general, ethical issues related to testing situation when older adults with MCI are involved, include tensions among *ethical principles* such as truth telling (honest and complete disclosure of relevant information), *autonomy* (the individual's right and capacity to decide what happens in their care), and *non-maleficence* (the professional's duty to avoid harm).

By not involving older adults with MCI, ethics related to **Disclosing the Diagnosis** and **Stigmatization** have been avoided.

Ethical principles for involving people with Subjective Cognitive Impairment as study participants in research are:

- respecting users' abilities to make decisions, securing consent to participate from proxy decision-makers (e.g., family members)
- respect for persons, beneficence, and justice through the **informed consent/acceptance process.**

For considering that older adults with subjective cognitive impairment can be involved, we have accounted for the following principles:

- The principle of respect for persons - individuals should be treated as autonomous agents, and people with diminished autonomy are entitled to protection;
- The principle of beneficence - is an obligation to maximize possible benefits and minimize possible harms of research;
- The principle of justice requires that equals be treated equally.

7.2. Ethical evaluation of E4L functionality

- ✓ E4l expect a low level of knowledge of computers and the Internet that some people may not have, as the technological gap (the first digital divide or the grey divide, is shrinking). Though, this is a relative matter, a training and E4L manuals have been designed.
- ✓ Is the Ella technology and Anne application being designed to be accessible? This question is going to be addressed in the deliverable concerning exploitation through, the fact that Emma tablet devices requirements, i.e. price, can be seen as a limitation to the accessibility of Anne, The Virtual Assistant.
- ✓ Are Ella and Anne easy to use for older adults and/or citizens with disabilities? Yes, due to the efforts of the technical teams, non-functional requirements for Ella and Anne are implemented, such as contrast, big letters, no arrows for back and forward function, one button and others. They are discussed in the deliverables concerning field-trials.
- ✓ The E4L has been designed taking into account values such as human wellbeing, and dignity
- ✓ The E4L system empowers older adults& reduces anxieties related to their safeness.
- ✓ The E4L system does not violate human dignity.

8. Further initiatives

ANA Foundation has decided to take upon an innovative approach: the informal involvement of older adults to consult on any issue of concern regarding ethics.

The inspiration came from the so far experience in field testing and from the new AAL ethics guidelines and to further ensure that the articles 13 and 14 of the GDPR

are respected, and that sufficient information is provided to the senior end-users in order to take an informed decision.

That will also re-assure ANA Foundation's engagement to follow an ethical dialogue with the users.

Hence, ANA has decided that for further projects and initiatives which concern ethics, to involve between two and five older adults to consult on the informed consent and the presentations prepared for the end-users in order to conduct an ante-evaluation with respect to the degree to which the text, the terminology, the structure of the texts, the letter size and other relevant aspects, answer to the age-related impairments and vulnerabilities of the group of age 65 and over to whom we address.

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Federal Act on Data Protection (FADP) of 19 June 1992 (status as of 1 January 2014)

The GDPR and its consequences for Switzerland; https://www.edoeb.admin.ch/dam/edoeb/en/dokumente/2018/The%20GDPR%20and%20its%20consequences%20for%20Switzerland.pdf.download.pdf/The%20GDPR%20and%20its%20consequences%20for%20Switzerland.pdf

The Netherlands:

Wet Bescherming Persoonsgegevens (WBP) / Personal Data Protection Act (6 July, 2000) With regard to this law it's important the gathered information in the project can not be easily used to identify a person. In addition the emphasis is on the voluntary consent based on complete informatio about data collection and storage.

Wet medisch-wetenschappelijk onderzoek met mensen (WMO) / Law on medical research with human subjects (26 February, 1998) If a study falls under the scope of the Medical Research Involving Human Subjects Act (WMO) then it must undergo a prior review by an accredited Medical Ethical Reviewing Committee (MREC) or the Central Committee on Research Involving Human Subjects (CCMO). Research falls under the WMO if the following criteria are met: 1. It concerns medical/scientific research and 2. Participants are subject to procedures or are required to follow rules of behaviour.

Romania:

Law No. 190/2018 Implementing the General Data Protection Regulation (Regulation (EU) 2016/679) ('the Law'), published in the Official Gazette No. 651 of 26 July 2018.

LAW no. 206 from 27 May 2004 regarding the good conduct in scientific research, technological development and innovation are regulated the good conduct in scientific research and the deviations from the rules of good conduct.

Code of Ethics, provided by Law no. 319/2003 regarding the Statute of Research and Development Staff.

10. Appendix

Appendix 1 Explanation on the Subjective Cognitive Impairment

Over 20% of adults aged 60 and over suffer from a mental or neurological disorder (excluding headache disorders) and 6.6% of all disability (disability adjusted life years-DALYs) among people over 60 years is attributed to mental and neurological disorders (WHO, 2021) https://www.who.int/news-room/fact-sheets/detail/mental-health-of-older-adults .

Older people may face risk factors that are more common in later life, like a significant ongoing loss in cognition and a decline in functional ability. Older adults are also vulnerable to elder abuse. The abuse could be: physical, emotional, verbal, financial, abandonment, neglect. These come with serious losses of dignity and respect. Abuse can happen anywhere, in the older person's home, a family member's house, an assisted living facility, or a nursing home.

There are four cognitive severity stages:

No Cognitive Impairment (NCI) Individuals perceive no decline in cognition and no decline in complex skills that rely on their cognitive abilities. ...

Subjective Cognitive Impairment (SCI) is the self-reported experience of worsening or more frequent confusion or memory loss.... Subjective cognitive impairment (SCI), also known as subjective memory disorder, is when a patient reports a worsening of their thinking abilities, including memory, but the decline cannot be verified by standard tests.

Mild Cognitive Impairment (MCI) causes cognitive changes that are serious enough to be noticed to the person affected and to family members and friends,

People living with MCI, especially MCI involving memory problems, are more likely to develop Alzheimer’s disease or other dementias than people without MCI.

Signs of MCI include:

Losing things often

Forgetting to go to events or appointments

Having more trouble coming up with words than other people of the same age

Dementia.

We have to prepare health strategies and tools to meet the specific needs of older populations, including:

Ethical standards and procedures based on respecting the human rights standards dedicated to people with mental illness and their caregivers;

Training for health professionals and people working with older adults in providing care for older people;

Health promotion, by creating living conditions and environments that support wellbeing and allow people to lead a healthy life;

Prompt identification and treatment of mental, cognitive disorders and

Technology-enhanced interventions for older adults. Research (Cangelosi and Sorell, 2014) https://pubmed.ncbi.nlm.nih.gov/25062353/ shows that older adults may gain significant mental health benefits from health resources made available through emerging modern technologies, especially because this population is becoming more Internet savvy.

Appendix 2 Introductory letter to the senior volunteers

What are the aims of the Ella4Life project? Ella4Life is a multinational and multidisciplinary project funded by the AAL Joint Program of The European Commission that aims to give the senior persons a solution that offers the possibility to improve their self-management, wellbeing and independence and in particular for those seniors with a chronic condition to increase their comfort by providing constant connection with the relevant professionals and informal caregivers that Ella4Life will inform in case of emergency.

For achieving that, the project's medico-social and technical researchers will create an integrated prototype, that will bring together already existing solutions that are functioning digital assistants mostly for elderly people - Emma and Anne to which a sensor technology for use in the bath and in the chair will be integrated.

• Emma is a mobile solution and has a working connection with several e-health self-management solutions. She stimulates her users to lead an active, less sedentary and healthy life. Besides stimulating self-management, she also connects the user to their informal caregiver and the professionals within several fields of chronic diseases. This connection makes it possible to monitor the disease and act and instruct when needed and not when planned.

• Anne is an avatar that supports elderly people with daily structure and communicates, speech-controlled, with home automation. She reads the news and enhances for example video-communication.

• Integration of Anne, Emma and the sensor technology in Ella4Life will result in an integral solution with a combined backbone. One solution supporting care and cure, for when they are on their way as well as at home, for health and wellbeing, for formal and informal caregivers

What would be your role and contribution expected in the Ella4Life project?

You will voluntarily participate in all the activities of the project for which your opinions and recommendations as end-user are highly needed for detecting your needs, opinions and preferences for the services to be created and offered by the Ella4Llife integrated solution, thus contributing to the progressive improvement of the prototype, as well as to its testing and validation at your own home.

The investigators of the ANA / LLI / MOU / HSL project team will explain your role in each working session, and how to use the Ella4Life components, or the documents used for collecting your opinions and suggestions about platform's usability and usefulness.

You will receive group and individual training at the premises of the end-user organizations or at home (based on your preferences) before the testing period for the use of the platform. Also, it will be demonstrated to you how to do the collection of the feedback of usability in an autonomous way. Deliverable 1.5 Ethical Guide and Data Protection Plan Page 24/25

It is desired that you test the solution once per day (in the 1st pilot) / four times a week (during the 2nd and 3rd pilot). You will be asked to fill in at certain intervals the questionnaires provided to you for helping us with your feedback. Also, you will be contacted for short interviews, which will also help us improve the platform's performance.

Please note that any testing session during the project running doesn't mean at all that your capacities or skills will be tested, but only the functioning of the prototype and the usability and usefulness of the services it will provide.

How many people will take part in the study?

About 100 voluntary end-users are expected to take part in this study in three of the piloting countries (NL, PL, RO) and 30-50 participants in CH. Furthermore, in Netherlands 100 end-users with take part in a control group. All the end-users will be involved in the project's activities by the end-user's organizations, in their designated areas.

Are there benefits for you to take part as voluntary end-user in the project?

Your contribution to this study will be for research purposes only.

According to the AAL projects financial provisions, you will not be paid for participating in this study.

You should not expect to widely and definitely improve your state as a result of participating in this project and using the services it creates.

However, by participating in this project you will get new information about you and, about the newly created, vanguard virtual methods that may help you improve your quality of life, by remaining active.

Also, we hope that your involvement into a multinational research project aiming at improving the quality of life of seniors at their own home may represent a moral reward for you. Deliverable 1.5 Ethical Guide and Data Protection Plan Page 25/25 7.3

Appendix 3: Informed Consent

Organized by ANA / LLI / MOU / HSL

Within the project "Ella4Life – your Virtual Personal Assistant for home and on the road" The present study aims to evaluate Ella4Life platform operability and to identify active senior's preferences regarding its features. The study will be conducted by ANA / LLI / MOU / HSL specialists, within the project "Ella4Life – your Virtual Personal Assistant for home and on the road", financed through the AAL 2017 programme. Your involvement in the study will consist in participating in the pilot – where you will test how the online platform works, then you will fill in a questionnaire. The questionnaire is anonymous. The pilot will be conducted by (name of the responsible prson), representative of the organization ANA / LLI / MOU / HSL Your participation is voluntarily and you can drop out at any time. The training will last about 40-60 minutes (TBD) during which you will see a presentation of the projects, you will be instructed on how the system operates, you will test by yourselves and you will fill in a questionnaire. The information you will share with us if you participate in this study will be kept completely confidential to the full extent of the law, according to the Romanian / Swiss / Dutch / Polish legislation. All the collected data will be processed and stored in strict confidentiality and your identity will never be revealed. If you have any questions about this study, please contact [NAMES OF PIS, PHONE NUMBERS AND EMAIL ADDRESSES].

Your signature on this consent form indicates your agreement to participate in this study. You will be given a copy of this form to keep, whether you agree to participate or not.

The second signed consent form will be kept by the researcher.

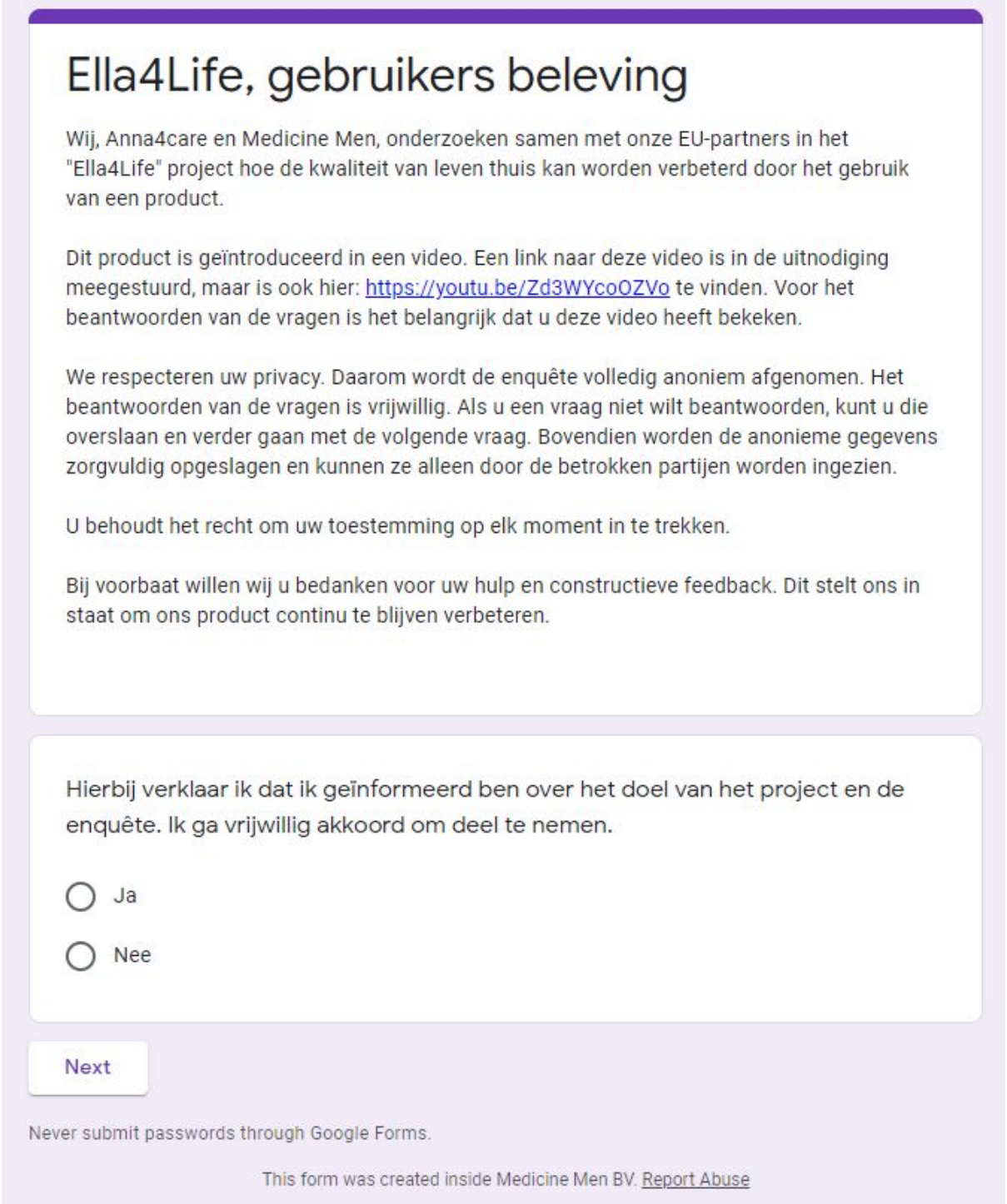
Thank you very much!

Name: _____

Signature: _____

Date: _____

Appendix 4 Netherlands Informed Consent and Questionnaire



Ella4Life, gebruikers beleving

Wij, Anna4care en Medicine Men, onderzoeken samen met onze EU-partners in het "Ella4Life" project hoe de kwaliteit van leven thuis kan worden verbeterd door het gebruik van een product.

Dit product is geïntroduceerd in een video. Een link naar deze video is in de uitnodiging meegestuurd, maar is ook hier: https://youtu.be/Zd3WYcoOZVo te vinden. Voor het beantwoorden van de vragen is het belangrijk dat u deze video heeft bekeken.

We respecteren uw privacy. Daarom wordt de enquête volledig anoniem afgenomen. Het beantwoorden van de vragen is vrijwillig. Als u een vraag niet wilt beantwoorden, kunt u die overslaan en verder gaan met de volgende vraag. Bovendien worden de anonieme gegevens zorgvuldig opgeslagen en kunnen ze alleen door de betrokken partijen worden ingezien.

U behoudt het recht om uw toestemming op elk moment in te trekken.

Bij voorbaat willen wij u bedanken voor uw hulp en constructieve feedback. Dit stelt ons in staat om ons product continu te blijven verbeteren.

Hierbij verklaar ik dat ik geïnformeerd ben over het doel van het project en de enquête. Ik ga vrijwillig akkoord om deel te nemen.

- ◯ Ja
- ◯ Nee

Next

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Ella4Life, gebruikers beleving

Algemeen

Geboortejaar

- 1920-1930
- 1931-1940
- 1941-1950
- 1951-1960
- 1961-1970
- 1971-1980
- 1981-1990
- 1991-2000
- 2001-2010

Geslacht, ik ben een...

- Vrouw
- Man
- Anders

Uw huidige burgerlijke staat is?

- Gehuwd
- Relatie
- Alleenstaand
- Weduw

Uit hoeveel mensen (inclusief uzelf) bestaat uw huishouden?

Your answer

Kunt u aangeven wat uw hoogste behaalde opleidingsniveau is?

- ◯ Geen opleiding
- ◯ Lager onderwijs
- ◯ Voortgezet onderwijs
- ◯ Hoger beroepsonderwijs (HBO)
- ◯ Wetenschappelijk onderwijs (WO)

Hoe zou u uw gezondheidstoestand in de afgelopen 4 weken omschrijven?

- ◯ Uitstekend
- ◯ Goed
- ◯ Normaal
- ◯ Slecht
- ◯ Heel slecht

In hoeverre heeft u de afgelopen 4 weken problemen gehad door uw lichamelijke gezondheid in het dagelijks leven?

- ◯ Helemaal niet
- ◯ Weinig
- ◯ Veel
- ◯ Heel veel

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Ella4Life, gebruikers beleving

Indruk van het product

U heeft de video gezien, kunt u het product dat in de video wordt gepresenteerd beoordelen?
Link naar de video: https://youtu.be/Zd3WYcoOZVo

U heeft de video gezien, kunt u het product dat in de video wordt gepresenteerd beoordelen?

	Mee eens	Gedeeltelijk mee eens	Neutraal	Gedeeltelijk oneens	Oneens
Verwacht u dat het product gebruiksvriendelijk is?	○	○	○	○	○
Ik beschouw het product als nuttig	○	○	○	○	○
Het concept van het product is gemakkelijk te begrijpen.	○	○	○	○	○
Met behulp van het product kan ik mijn doelen bereiken.	○	○	○	○	○

Kunt u uw bovenstaande antwoorden motiveren?

Your answer

Back Next

Ella4Life, gebruikers beleving

Indruk van potentieel gebruik

Wilt u aangeven hoe u het gebruik denkt te ervaren?

	Mee eens	Gedeeltelijk mee eens	Neutraal	Gedeeltelijk oneens	Oneens
Het gebruik van het product zal mij enthousiasmeren.	○	○	○	○	○
Het product zal me irriteren.	○	○	○	○	○
Het product zal mij rust geven.	○	○	○	○	○
het gebruik van het product zal mij nerveus maken.	○	○	○	○	○
Het product zal me een gelukkig gevoel geven.	○	○	○	○	○
Het product zal mij frustreren.	○	○	○	○	○
Als ik het product ga gebruiken, zal ik opgewekt zijn.	○	○	○	○	○

Kunt u de bovenstaande antwoorden motiveren? Of kunt u iets meer vertellen over hoe u het gebruik van het product verwacht te ervaren?

Your answer

Back Next

Ella4Life, gebruikers beleving

Functie & functionaliteiten

Wilt u het product beoordelen op de toegevoegde waarde voor u?

	Mee eens	Gedeeltelijk mee eens	Neutraal	Gedeeltelijk oneens	Oneens
Er is geen alternatief voor dit product.	○	○	○	○	○
De activiteiten coach, de stappenteller met coach, is een toevoeging voor het complete product.	○	○	○	○	○
Het design van de activiteiten coach ziet er goed uit.	○	○	○	○	○
Anne, de persoonlijke digitale assistent is een toevoeging voor het complete product.	○	○	○	○	○
Het design van Anne ziet er goed uit.	○	○	○	○	○

Wilt u uw bovenstaande antwoorden motiveren?

Your answer

Kunt u de volgende functionaliteiten beoordelen op belangrijkheid, schaal 1-5?

	1: Erg onbelangrijk	2: Onbelangrijk	3: Neutraal	4: Belangrijk	5: Erg belangrijk
Beeldbel optie	○	○	○	○	○
Activiteit bijhouden	○	○	○	○	○
Activiteit coaching	○	○	○	○	○
Betrekken van een maatje/mantelzorger/coach bij uw activiteit	○	○	○	○	○
Planning management (Agenda)	○	○	○	○	○
Medicatie management	○	○	○	○	○
Gebruik van radio of andere media (nieuws/weerbericht)	○	○	○	○	○
Digitale spelletjes	○	○	○	○	○

Kunt u deze beoordeling toelichten?

Your answer

Wat vind u van het product, tot nu toe?

	1	2	3	4	5	6	7	8	9	10	
Heel slecht	○	○	○	○	○	○	○	○	○	○	Heel goed

Zou u gebruik willen maken van het product?

	1	2	3	4	5	
Zeker niet	○	○	○	○	○	Ja, heel graag

Zou u willen motiveren waarom u wel of geen gebruik zou willen maken van het product?

Your answer

Wat vindt u goed aan het product?

Your answer

Wat zou er verbeterd moeten worden aan het product?

Your answer

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Appendix 5 Romania's Informed Consent and Questionnaire

1. *

ANA ASLAN INTERNATIONAL FOUNDATION

INFORMARE
PRIVIND PRELUCRAREA DATELOR CU CARACTER PERSONAL

Având în vedere noile reglementări cu privire la protecția datelor cu caracter personal, introduse prin Regulamentul UE 2016/679, "GDPR", ce reprezintă baza legislației privind prelucrarea datelor cu caracter personal și a protecției acestor date pentru toate țările membre UE, dorim să vă garantăm angajamentul nostru ferm de a procesa datele Dvs. personale în mod transparent, securizat și cu respectarea tuturor drepturilor de care beneficiați conform legii. În acest scop, regăsiți în continuare elementele principale pe care considerăm că este util să le cunoașteți pe această temă, în calitatea Dvs. de "persoană vizată".

Ce înseamnă prelucrarea datelor

Conform Regulamentului UE 2016/679, prin „prelucrare de date" se înțelege orice operațiune sau set de operațiuni efectuate asupra datelor cu caracter personal sau asupra seturilor de date cu caracter personal, cu sau fără utilizarea de mijloace automatizate, cum ar fi colectarea, înregistrarea, organizarea, structurarea, stocarea, adaptarea sau modificarea, extragerea, consultarea, utilizarea, divulgarea prin transmitere, diseminarea sau punerea la dispoziție în orice alt mod, alinierea sau combinarea, restricționarea, ștergerea sau distrugerea.

Informații privind operatorul datelor Dvs.

În calitatea sa de operator de date cu caracter personal, Fundația Ana Aslan Internațional va avea întotdeauna în vedere ca prelucrarea de date să fie caracterizată de legalitate, echitate și transparență, datele solicitate fiind adecvate, relevante și limitate la ceea ce este necesar în raport cu scopurile în care sunt prelucrate.

Datele operatorului: Fundația Ana Aslan Internațional, P-ța M. Kogalniceanu, nr. 1, ap. 17, sect. 5, București, tel/fax: 021-312.46.96, e-mail: office@anaaslanacademy.ro.

Date de contact ale Responsabilului cu protecția datelor: P-ța M. Kogalniceanu, nr. 1, ap. 17, sect. 5, București, tel/fax: 021-312.46.96, e-mail: dpo@anaaslanacademy.ro.

Ce date cu caracter personal prelucrăm ? În ce scopuri ?

Prin Formularul de comandă colectăm următoarele tipuri de date cu caracter personal:

- ✓ Date de identificare: numele și prenumele, serie și număr CI
- ✓ Date de contact: adresa de e-mail, numărul de telefon, adresa
- ✓ Date legate de plăți, care se reflectă în extrasele noastre bancare
- ✓ Date de trafic: IP, cookie, în timpul sesiunilor online

Datele menționate mai sus sunt prelucrate în următoarele scopuri:

- ✓ Pentru emiterea facturilor
- ✓ Pentru comunicari referitoare la comandă
- ✓ Pentru expedierea produselor, dacă se optează pentru această variantă

Unde se transmit datele Dvs. personale ?

Datele Dvs. personale vor fi prelucrate și păstrate în siguranță de către Fundația Ana Aslan Internațional.
Datele din facturi vor fi transmise doar către autorități și firma de Contabilitate, iar datele de livrare, către firma de curierat.
Datele nu vor fi transmise către țări terțe și/sau organizații internaționale.

Pe ce perioadă păstrăm datele ?

Datele cu caracter personal colectate în scopul facturării, precum și datele legate de plata comenzii, vor fi păstrate 10 ani, conform Legislației fiscale în vigoare.

Datele de trafic (IP, cookie) vor fi păstrate doar pe durata sesiunilor online, conform Politicii referitoare la cookie.

Ce se întâmplă dacă nu doriți ca datele Dvs. să fie prelucrate ?

În situația în care nu doriți ca datele Dvs. personale să fie prelucrate, vom fi în imposibilitatea de a procesa comanda Dvs. Acordul sau opoziția Dvs. privind prelucrarea acestor date vor fi validate prin bifarea casuțelor corespunzătoare (Sunt de acord / Nu sunt de acord).

Care sunt drepturile Dvs. cu privire la datele personale ?

Conform prevederilor Regulamentului UE 2016/679, aveți dreptul de a solicita accesul la datele Dvs., rectificarea sau ștergerea lor, restricționarea prelucrării, aveți dreptul de a vă opune prelucrării, precum și dreptul la portabilitatea datelor. De asemenea, aveți dreptul de a depune o plângere în fața autorității de supraveghere (ANSPDCP).

Mark only one oval.

◯ Am citit documentul si Sunt de acord cu termenii Informarii privind prelucrarea datelor cu caracter personal

Chestionar Anne

Vă rugăm urmăriți video-ul de prezentare a video-ul de prezentare Asistent Virtual Anne la link-ul de mai jos și reveniți în această pagină pentru a răspunde la întrebări.

Mulțumim!

2. 1. Ați urmărit video-ul de prezentare a Noului Asistent Virtual Anne. Cum vi s-a părut această prezentare? *

Mark only one oval.

	1	2	3	4	5	
Deloc interesantă	◯	◯	◯	◯	◯	Foarte interesantă

3. 2. În ce măsură credeţi că acest produs vă este util? *

Mark only one oval.

	1	2	3	4	5	
Deloc nu imi e util	◯	◯	◯	◯	◯	În foarte mare măsură util

4. 3. În ce măsură credeţi că este util altora? *

Mark only one oval.

	1	2	3	4	5	
deloc util	◯	◯	◯	◯	◯	în foarte mare măsură util

5. 4. Ce vi se pare util la Anne? *

Mark only one oval per row.

	Util	Deloc util	Nu îmi dau seama
Sugestiile de activităţi	◯	◯	◯
Agenda	◯	◯	◯
Fotografiile	◯	◯	◯
Radio	◯	◯	◯
Ştirile	◯	◯	◯
Jocuri	◯	◯	◯

6. 5. În ce măsură sunteţi de acord cu următoarele funcţii oferite de Anne *

Mark only one oval per row.

	Total dezacord	În mică măsură de acord	În mare măsură de acord	Total acord
Îmi reaminteşte ce am de făcut	◯	◯	◯	◯
Îmi place că îmi sugerează lucruri noi	◯	◯	◯	◯
Anne m-ar face mai activ fizic	◯	◯	◯	◯
Anne m-ar face mai activ social	◯	◯	◯	◯
Anne mă face să mă simt pasiv	◯	◯	◯	◯
Sunt curioasă să testez Anne	◯	◯	◯	◯
Cred că Anne este potrivit pentru o rudă sau cunoştinţă de-a mea	◯	◯	◯	◯

7. 6. Vă rugăm să ne spuneţi vârsta dvs? *

_____

8. 7. Care dintre următoarele tehnologii/produse le folosiți? *

Mark only one oval per row.

	Zilnic	Săptămânal	Rar	Niciodată
Masina de spalat vase	◯	◯	◯	◯
Telefon mobil smart	◯	◯	◯	◯
Facebook	◯	◯	◯	◯
Whatsapp	◯	◯	◯	◯
Ceas sau brățară smart (care înregistrează paramatri de sănătate)	◯	◯	◯	◯
Radio	◯	◯	◯	◯
Calculator/ tableta	◯	◯	◯	◯
Conduceti masina	◯	◯	◯	◯
Televizor	◯	◯	◯	◯

9. 8. Vă rugăm să ne spuneți sexul dvs? *

Tick all that apply.

- ☐ Feminim
- ☐ Masculin

10. 9. Vă rugăm să ne spuneţi ultima şcoală absolvită *

Mark only one oval.

- ◯ 4 clase
- ◯ 8 clase
- ◯ Scoala profesionala
- ◯ Liceul
- ◯ Universitate

11. 10. Locuiţi împreună cu cineva în gospodărie? *

Mark only one oval.

- ◯ Singur
- ◯ Soţul/ soţia sau concubinaj
- ◯ cu familia extinsă
- ◯ Altă situaţie

12. 11. Sunteti o persoana religioasa? *

Mark only one oval.

- ◯ Da, merg la biserica si ma rog
- ◯ Merg la biserica dar nu ma rog
- ◯ Ma rog dar merg mai rar la biserica
- ◯ Rareori merg la biserica si rareori ma ror
- ◯ Mai degraba nu
- ◯ Categoric nu.

13. 12. Care este venitul dvs.? *

Mark only one oval.

- ◯ Sub 1500 Ron
- ◯ intre 1500 si 2500 Ron
- ◯ Intre 2500 si 3500 Ron
- ◯ Peste 3500 Ron

14. 13. Cum ați descrie starea sănătății dvs. în ultimele 4 săptămâni la domiciliu? *

Mark only one oval.

- ◯ Excelentă
- ◯ Foarte bună
- ◯ Bună
- ◯ Mai puțin bună
- ◯ Rea
- ◯ Foarte rea

15. 14. În ce măsură sănătatea fizică sau problemele psihice v-au afectat/ restricționat contactele normale cu membrii familiei sau cu prietenii în ultimele 4 săptămâni? *

Mark only one oval.

- ◯ Deloc
- ◯ Foarte puțin
- ◯ Moderat
- ◯ În mare măsură
- ◯ În foarte mare măsură

16. 15. În ce măsură probleme precum frica, depresia sau iritabilitatea v-au afectat în ultimele 4 săptămâni? *

Mark only one oval.

- ◯ Deloc
- ◯ Foarte puțin
- ◯ Moderat
- ◯ În mare măsură
- ◯ În foarte mare măsură

17. 16. După părerea dvs., în ce măsură uitați lucruri? (cheile, pașii unei rețete, o programare) *

Mark only one oval.

	1	2	3	4	5	
mai rar decat o data pe saptamana	◯	◯	◯	◯	◯	de cateva ori pe zi

18. 17. Sunt mândru de lucrurile pe care le-am realizat în viață. *

Mark only one oval.

	1	2	3	4	5	6	7	
Total dezacord	◯	◯	◯	◯	◯	◯	◯	total acord

19. 18 lau lucrurile neplacute așa cum sunt. *

Mark only one oval.

	1	2	3	4	5	6	7	
total dezacord	◯	◯	◯	◯	◯	◯	◯	total acord

20. 19. Mă preocupă lucrurile noi. *

Mark only one oval.

	1	2	3	4	5	6	7	
total dezacord	◯	◯	◯	◯	◯	◯	◯	total acord

21. 20. De obicei, găsesc ceva care să mă amuze. *

Mark only one oval.

	1	2	3	4	5	6	7	
total dezacord	◯	◯	◯	◯	◯	◯	◯	total acord

22. 21. Viața mea are sens *

Mark only one oval.

	1	2	3	4	5	6	7	
total dezacord	◯	◯	◯	◯	◯	◯	◯	total acord

23. Aveti de adaugat observatii sau sugestii?

24. 22. Daca sunteti disponibil sa fiți contactat pentru culegerea mai multor informații sau pentru a participa și in alte studii online sau telefonic vă rugăm să ne lăsați un contact (telefon/ FB / e-mail)

Appendix 6 Switzerland questionnaire

VICINO LUZERN

iHomeLab 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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