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D2.3: Ethics standards and data management plan

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[1] L = Legal agreement, O = Other, P = Plan, PR = Prototype, R = Report, U = User scenario

[2] PU = Public, PP = Restricted to other programme participants (including the Commission Services), RE = Restricted to a group specified by the consortium (including the Commission Services), CO = Confidential, only for members of the consortium (including the Commission Services)

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Table of Contents

List of figures

List of tables

No table of figures entries found.

List of acronyms (alphabetically)

Acronym	Full name
CE	Conformité Européenne
CNBC	Cyprus National Bioethics Committee
DPO	Data Protection Officer
EC	Ethics Committee
EU	European Union
GDPR	General Data Protection Regulation
GDS	Geriatric Depression Scale
IEC	Institutional Ethics Committees
MCI	Mild Cognitive Impairment
NAMMD	National Agency for Medicines and Medical Devices
NCD	Neurocognitive Disorder
NCMMD	National Committee of Medicines and Medical Devices
NEC	National Ethics Committee
Req	Requirement
RMCAS	ReMember – Me Cognitive Assessment Scale

Executive Summary

This document presents the ethical principles and standards that will be adopted by the ReMember – Me Consortium throughout the project implementation. It also contains the data management plan for the ReMember – Me project. This deliverable will serve as a common direction and ethical protocol for all end user organisations during field trials.

Chapter I describes the general ethical framework and the existing European Union regulations, declarations and conventions under which the project will be carried out.

Chapter II is a thorough description of how the ReMember- Me project will comply with the ethical principles, standards, national laws in the pilot sites and the General Data Protection Regulation.

Chapter III gives information about data that is going to be collected during the field trials as well as its handling and management by project partners.

Comment by authors: Since important designing activities of the ReMember – Me system are still ongoing this deliverable is a dynamic document and shall be subject to amendments.

Introduction

Project overview

ReMember – Me is a multinational project funded by the Active Assisted Living Joint Programme that aims to detect and prevent cognitive decline early on in older adults. Cognitive decline or cognitive impairment is defined as a state in which a person has difficulties in remembering, concentrating, learning new things, or making decisions which affect their everyday life. Cognitive decline ranges from mild to severe (major). When people have mild cognitive impairment (or else Mild Neurocognitive Disorder hereafter Mild NCD), they have difficulties in at least one of the cognitive domains mentioned above (e.g., remembering, concentrating, etc.) but these difficulties do not affect significantly their ability to do everyday activities independently (e.g., paying bills or taking medication). When people have severe cognitive impairment (or else Major NCD) they have significant difficulties in at least one of the cognitive domains mentioned above (e.g., remembering, concentrating, etc.) and these difficulties hinder their ability to do everyday activities independently (e.g., they need help to pay bills or take their medication). Early on diagnosis of cognitive decline (Mild Cognitive Impairment state hereafter MCI or before Mild Cognitive Impairment is manifested) is very important. Being diagnosed early on with cognitive decline gives a person a chance for improvement or maintenance of their cognitive function through rehabilitation activities and counteractive actions.

ReMember – Me is a smart system that integrates feedback from a social robot, tablet, fitness tracker and sleep analyser. It offers baseline assessment for cognitive impairment, detection exercises, stimulating games, and socializing through its Meet people social platform.

1. General ethical framework

The four principles

Throughout the implementation of the ReMember – Me project, from its co-creation, design and conceptualisation, to development and testing, the ReMember – Me consortium will be guided by the four principles of Biomedical Ethics originally defined by Beauchamp and Childress. They are as follows:

Autonomy – The right for a participant to make his/ her own fully informed decision and choice whether to take part in the project or not. That is, primary system users are informed about the possible risks and benefits, and likelihood of success. Therefore, participation in the ReMember – Me project and testing the system in all its phases will be determined by signing an explicit consent. Prior to signing the consent form, project participants will be given clear and full information about the project and their involvement in it.

Beneficence – General operation of the system and the research will be of benefit to the participant and to the good of society as a whole.

Non-maleficence – The general operation of the system will not intentionally create harm or injury to the participant and will not put him/her under some unreasonable or unacceptable risk.

Justice – The research and the general operation of the system will incorporate equality and fairness. No bias based on age, gender, ethnic or social origin, culture, nationality, or any other social prejudice will be promoted.

The Charter of Fundamental Rights of the EU

The Charter of Fundamental Rights of the EU defines the fundamental rights and freedoms of EU citizens. It has several articles that are important for the rightful implementation of the ReMember – Me project:

Article 1: Human dignity

Human dignity is inviolable. It must be respected and protected.

Article 3: Right to the integrity of the person

1. Everyone has the right to respect for his or her physical and mental integrity.

2. In the fields of medicine and biology, the following must be respected in particular:

(a) the free and informed consent of the person concerned, according to the procedures laid down by law;

(b) the prohibition of eugenic practices, in particular those aiming at the selection of persons;

(c) the prohibition on making the human body and its parts as such a source of financial gain;

(d) the prohibition of the reproductive cloning of human beings.

Article 7: Respect for private and family life

Everyone has the right to respect for his or her private and family life, home and communications.

Article 8: Protection of personal data

1. Everyone has the right to the protection of personal data concerning him or her.

2. Such data must be processed fairly for specified purposes and on the basis of the consent of the person concerned or some other legitimate basis laid down by law.

Everyone has the right of access to data which has been collected concerning him or her, and the right to have it rectified.

3. Compliance with these rules shall be subject to control by an independent authority.

Article 13: Freedom of the arts and sciences

The arts and scientific research shall be free of constraint. Academic freedom shall be respected.

Article 21: Non-discrimination

1. Any discrimination based on any ground such as sex, race, colour, ethnic or social origin, genetic features, language, religion or belief, political or any other opinion, membership of a national minority, property, birth, disability, age or sexual orientation shall be prohibited.

2. Within the scope of application of the Treaties and without prejudice to any of their specific provisions, any discrimination on grounds of nationality shall be prohibited.

Article 23: Equality between women and men

Equality between women and men must be ensured in all areas, including employment, work and pay.

The principle of equality shall not prevent the maintenance or adoption of measures providing for specific advantages in favour of the under-represented sex.

Article 25: The rights of the elderly

The Union recognises and respects the rights of the elderly to lead a life of dignity and independence and to participate in social and cultural life.

The Nuremberg Code

The Nuremberg Code is a set of ten guiding ethics research principles related to human experimentation. It was the result of the Nuremberg Military Tribunals in 1947. It had a significant impact on conducting clinical research around the world. The Nuremberg Code, consisting of ten points, described the rights of research subjects. Rule number one points out the importance of voluntary consent freely given by research participants. That is, human subjects should have legal capacity to give consent and be left to exercise their power of free choice. Therefore, they need to be informed about the nature, duration, methods and purpose of research as well as all possible risks and dangers for them arising from it before they make their choice for participation in it. The other rules state protecting the integrity of human subjects from injuries, disabilities or death, as well as their right to withdraw from participation in the experiment.

Declaration of Helsinki from 1964

The Declaration of Helsinki is another pivotal document for modern research which came as a result of the atrocities done by German medical researchers in Nazi concentration camps during the World War II. The World Medical Association sets certain ethical principles aimed at the protection of human subjects in medical research. Ever since its adoption in 1964, the Declaration of Helsinki has served as standard in medical research ethics. All consortium partners agree to comply with it as well as all other national or EU legal and ethical requirements.

This means that:

- All research subjects will be able to give informed consent to participate. MCI users will consult with their family members/ relatives and make the decision together;
- All subjects will be volunteers and will have the right to withdraw from the pilot trials at any time;
- Their personal data will be protected and kept confidential;
- Where applicable, research protocols will be submitted for evaluation and approval by national Bioethics Committees prior to the beginning of the study.
- After receiving detailed information about the project, participants will receive in their native language an information letter containing the following information:
- Plain and easy-to-understand written description of the project i.e. its name, nature, funding sources, and duration;
- The project objectives, project's phases and their duration, testing procedures i.e. research methods;
- Anticipated benefits for research subjects, potential risks of the study, and any discomfort it may entail will be described too;
- The information letter (Annex 1) and the explicit consent form (Annex 2) conform to the latest revised version of the Declaration of Helsinki.

European Union regulations

The ReMember – Me consortium endorses the following EU guidelines and regulations and commits to respect them.

The Convention for the Protection of Human Rights and Fundamental Freedoms

The right to privacy is part of the 1950 Convention for the Protection of Human Rights and Fundamental Freedoms better known as the European Convention on Human Rights. Article 8 states:

'Everyone has the right to respect for his private and family life, his home and his correspondence'

General Data Protection Regulation

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 hereafter GDPR) is the toughest security and privacy law in the world. As of May 2018, the GDPR is applicable in all Member States in the European Union (hereafter EU) as well as in the countries in the European Economic Area. However, it is far more reaching in its scope because it imposes obligations on organisations located anywhere in the world, as long as they collect data related to people in the EU. The GDPR lays down the rules related to processing of personal data and its free movement.

Data protection is a fundamental right. Article 8(1) of the Charter of Fundamental Rights of the European Union and Article 16(1) of the Treaty on the Functioning of the European Union state that everyone has the right to the protection of personal data concerning him or her. The GDPR grants individuals several rights that must be guarded by any actor who processes personal information. These individual rights include the following:

The right to be informed – Data subjects must be informed by the data controller about all personal data that is collected from them, purposes of the processing, legal basis for the processing, as well as the period for which the personal information will be stored.

The right to access – The data controller must supply data subjects with a copy of all the data they have collected from them.

The right to rectification – Data controllers must correct any data that a data subject feels are incorrect, inaccurate or complete data that an individual feels is incomplete.

The right to erasure – Data subjects has the right to erasure i.e. the 'right to be forgotten'. Article 17 of the GDPR states that personal data must be erased by the data controller when consent has been withdrawn, there is unlawful processing, personal data is no longer necessary in relation to the purposes for which it was collected.

The right to restrict processing – Data subjects have the right to restrict processing of their personal data.

The right to data portability – Article 20 of the GDPR defines data portability as the right of data subjects to receive their personal data in a machine-readable format and send it to another controller.

The right to object – Data subjects have the right to object to processing of their data for direct marketing purposes, profiling or on personal grounds at any time.

Rights in relation to automated decision making and profiling - Data subjects 'have the right not to be subject to a decision based solely on automated processing, including

profiling, which produces legal effects concerning him or her or similarly significantly affects him or her' (Article 22(1)).

Data protection principles

The GDPR has six key principles which constitute the core of the rules related to processing personal information. In addition, there is one more general principle which stands for "accountability". Article 5(2) of the GDPR defines accountability as the responsibility of the data controller to demonstrate compliance with the other six principles. The data protection principles are shown in Figure 1 below.

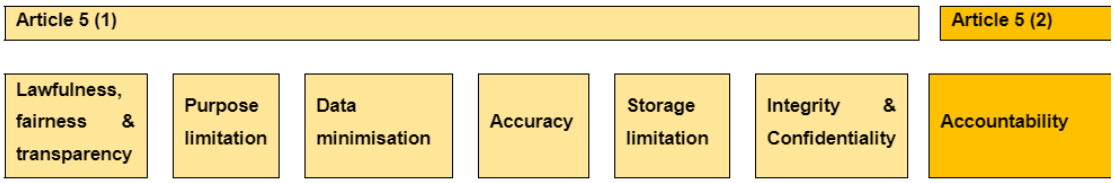

Figure 1. Overview of data protection principles

Lawfulness, fairness & transparency

Article 5 (1) states that personal data must be 'processed lawfully, fairly and in a transparent manner in relation to the data subject ('lawfulness, fairness and transparency');' Simply put, this principle means that data controllers must define their lawful basis for collecting and using personal data. In addition, they must use personal data in a way that is fair towards data subjects. For the processing of data to be fair, data subjects must know of the existence of a processing operation and must be given full and accurate information about it. Information that must be provided to data subjects is described in Articles 13 and 14 of the GDPR. In particular, according to Article 13, this information has to include:

- identity and contact details of the controller
- contact details of the data protection officer
- purposes of processing
- recipients of the personal data (if any)
- information if the controller intends to transfer the data to a third country or international organisation
- period for storage of personal data
- right to withdraw consent
- information about all other data subject' rights including the right to rectify their data, erase it or restrict its processing

Transparency is intertwined with fairness. Transparent processing requires data controllers to be open, honest and clear with data subjects from the start about who they are, and how and why they use their personal data. Using clear and plain language

is crucial in ensuring that people can understand the information given to them and make an informed choice.

Purpose limitation

Purpose limitation means that personal data must be collected for specified, explicit, and legitimate purposes. Further or additional processing of data in a way that is incompatible with these initial purposes is prohibited. The exemptions are for archiving purposes in the public interest, scientific or historical research purposes, or statistical purposes. Purposes of the processing must be included in the privacy policy or privacy notice for individuals.

Data minimisation

Article 5 (1c) states that personal data must be 'adequate, relevant and limited to what is necessary in relation to the purposes for which they are processed ('data minimisation')'. In general, this means that data controllers should identify the minimum amount of personal data they need to fulfil their purposes. Also, they should hold that much information, but not more than needed. So, to assess whether the data controller holds the right amount of personal data, they must first be clear about why they need it. They should also periodically review their processing to check that the personal data they collect is still relevant and adequate for their purposes, and delete anything they no longer need. This is closely intertwined with the storage limitation principle.

Accuracy

Personal data must be 'accurate and, where necessary, kept up to date; every reasonable step must be taken to ensure that personal data that are inaccurate, having regard to the purposes for which they are processed, are erased or rectified without delay ('accuracy');' (Article 5 (1d))

That is to say that organisations should ensure that the personal data they hold is correct, not misleading and accurate. This might require updating it whenever necessary. If organisations discover that personal data is not correct or misleading, they should take steps to correct it or erase it as soon as possible.

Storage limitation

Personal data must be:

'kept in a form which permits identification of data subjects for no longer than is necessary for the purposes for which the personal data are processed;' (Article 5 (1) (e)) The exact data retention period is not specified in the GDPR. The key point about this principle is that an organisation must not keep data for longer than it needs it. The only exemption is for public interest archiving, scientific or historical research, or statistical purposes (if the organisation has appropriate safeguards). Anonymised data can be kept for as long as the organisation wants i.e., indefinitely.

Integrity and confidentiality

Article 5 (1) (f) of the GDPR states that personal data shall be:

‘‘processed in a manner that ensures appropriate security of the personal data, including protection against unauthorised or unlawful processing and against accidental loss, destruction or damage, using appropriate technical or organisational measures (‘integrity and confidentiality’).’

This is the so-called ‘security principle’. It relates to the broad term of information security. Simply put, the security principle requires organisations to take the appropriate security measures in order to prevent the personal data they hold from being accidentally or deliberately compromised and breached. In this case, security refers to not only cybersecurity but also physical and organisational security measures.

The security principle is intertwined with Article 32 of the GDPR which gives more specifics on the security of processing data. Article 32 (1) says that:

‘Taking into account the state of the art, the costs of implementation and the nature, scope, context and purposes of processing as well as the risk of varying likelihood and severity for the rights and freedoms of natural persons, the controller and the processor shall implement appropriate technical and organisational measures to ensure a level of security appropriate to the risk’

In general, this means that both data controllers and processors must ensure a level of security that is appropriate to the risks that may be presented by their processing.

Accountability

There are two key elements in the accountability principle. The first element is that organisations are responsible for compliance with the GDPR. The second element is that they must be able to demonstrate their compliance. Demonstration of compliance may include adoption of certain security measures within the organisation, ensuring a good level of understanding and awareness of data protection amongst staff, designation of a data protection officer, performance of impact assessments etc.

Compliance with ethical principles and the GDPR in the ReMember – Me project

GDPR compliance

The GDPR describes the legal processing of and the rules for the free movement of personal data of EU individuals. According to it, Art. 4 (1), personal data is

‘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'

The ReMember – Me system will collect 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 ReMember – Me platform, the legal basis for processing this data will be explicit consent given by primary end users as defined in Art.9 (2) (a) and Art. 9 (2) (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. 3In addition, it should take into account the Union's objective under Article 179(1) TFEU of achieving a European Research Area. 4Scientific research purposes should also include studies conducted in the public interest in the area of public health'.

Data protection and privacy are priorities for the ReMember- Me system and services. Therefore, the ReMember – Me consortium commits to respecting the principles of lawfulness, transparency, and fairness laid down in the GDPR and to full compliance with it. 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:

Explicit consent – Processing of personal data will be done only after acquiring a signed explicit consent from primary users of the system. The explicit consent is discussed in detail in Chapter II, Section 5. Explicit consent (Annex 2).

Right of withdrawal – Throughout the whole ReMember – Me 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.

ReMember - Me researchers retain the right to request a participant to be no longer involved in the study only if an acquired condition constitutes them ineligible according

to the exclusion criteria and/or their participation is wrong, risky or immoral, even if the participant wishes to continue in the study. This condition may include but is not limited to, a severe/acute illness or injury, a significant decline in motor or cognitive ability, an acute acquired neurological impairment e.g. a stroke or loss of vision. Researchers' main goal upon making this decision will be to maintain a balance among the need to safeguard a participant and protect them from any procedure deemed risky for them but at the same time, avoid causing any discomfort to them as a result of excluding them from the study.

This is the reason why researchers will follow a specific exit strategy for the participants excluded not by their own choice which will include:

a) detailed explanation of the reason they are asked to stop their participation to the study,

b) provision of free exercise sheets, games and material in order for them to continue their training lasting at least for the total remaining time they would be asked to participate to the ReMember-Me study if they were not excluded and

c) a list of similar products available in the market in case they wish to continue their training.

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 the 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 ReMember – Me 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.

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.

Data minimisation – Only the minimum amount of data required for the project's purposes will be collected.

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.

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 ReMember – Me 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 ReMember – Me 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 data subjects at the consortium level such as the project DPO has been designated for the ReMember – Me consortium. This is Ms. Nellie Gospodinova from the Ana Aslan International Foundation.

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.' (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:

- Identity and contact details of the controller;
- Contact details of the DPO;
- Purposes of the processing;
- Legal basis for the processing;
- Categories of personal data that are collected;
- Recipients of the personal data if any;
- Period for which the personal data will be stored;
- Data subjects' rights;

Informing data subjects of their right to withdraw consent at any time, without affecting the lawfulness of processing based on consent before its withdrawal;

The privacy policy that the ReMember – Me consortium shall use is available in Annex 5. This privacy policy might be subject to future amendments due to the fact that the ReMember- Me system is under development.

National regulations on personal data protection

Pilot testing of the ReMember – Me system will be performed in Cyprus, Romania, Italy and Belgium. 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.

Cyprus

In its research and work, MATERIA follows the below described international policies and European regulations:

- Declaration of Helsinki
- Compliance with GDPR and other European legislations (GDPR Regulation 2016/679, Directive 2016/680, Directive 2002/58/EC)
- The Charter of Fundamental Rights of the EU
- GDPR Regulation 2016/679 and Directive 2016/680 on the protection of individuals with regard to the processing of personal data and on the free movement of such data"

- Directive 2002/58/EC on the “processing of personal data and the protection of privacy in the electronic communications sector”
- Data protection in Cyprus is monitored by the Office of Commissioner for Personal Data Protection and strictly reflects the EU General Data Protection Regulation enforced in May 2018. The Cyprus National Bioethics Committee is responsible for reviewing biomedical research involving human subjects in Cyprus.
- The following national legislation is applicable in Cyprus:
- Number 150(I) of 2001 Law providing for the establishment and function of the national bioethics committee in accordance with Article 52 of the Constitution
- The processing of personal data (protection of individuals) Law 2001 No 138 (I)
- The safeguarding and protection of the patients’ right law 2004 was valid until the establishment of Law 125(I)/2018.
- Law providing for the protection of Natural Person with regard to the processing of personal data and for the Free movement of such data of 2018 (Law 125(I)/2018)

Italy

In Italy, the data protection regulatory framework is composed of Legislative Decree 196/2003 containing the "Personal Data Protection Code" as amended by Legislative Decree 10 August 2018, no. 101 and of course the General Data Protection Regulation (EU) 2016/679.

The "Garante per la Protezione dei dati Personali" (GPDP) is the Italian Data Protection Authority; it is an independent administrative authority established by the so-called Privacy Law (Law No. 675 of 31 December 1996), then regulated by the Personal Data Protection Code and is the designated supervisory authority also for the purpose of implementing the General Data Protection Regulation (EU) 2016/679 (Art. 51).

Over the years, the GPDP has adopted a wide number of guidelines and measures regulating the interaction between data protection and health.Without claiming to be exhaustive, some of the most important provisions in this area include: "Prescriptions relating to the processing of genetic data" (Aut. gen. no. 8/2016); "Regulations concerning the processing of personal data for scientific research purposes" (General Authorisation No. 9/2016).

The GPDP on its institutional website page (https://www.garanteprivacy.it/) has created and keeps constantly updated several information pages related to the regulation of privacy in the health sector, including: Electronic Health File - Frequently Asked Questions; Online Referrals - Frequently Asked Questions; Compilation of the main provisions adopted in relation to the state of epidemiological emergency by Covid-19 having implications on the protection of personal data."

The Principles of personal data processing follow those specified in the General Data Protection Regulation (EU) 2016/679 (art.5: legality, fairness and transparency; purpose limitations; minimization of data; accuracy; data kept in a form that allows the identification of the data subjects for a period not exceeding the time required for the purposes for which the data are processed; integrity and confidentiality). Legality of Personal data processing is also defined according to the EU GDPR. Based on the accountability principle (art.24 par.1) the operator and the person empowered by it (art.28 par.4) implement technical and organizational measures appropriate to ensure data security and should be able to demonstrate that the implemented data security policies are in accordance with the GDPR. The amended (according to the EU GDPR) Italian ethical standards for collecting personal data for scientific research purposes have been recently published (G.U. 14/1/2019, n. 11). Guidelines for obtaining and demonstrating valid consent follow the Regulation 2016/679 (wp259 rev.01).

Belgium

REGULATION (EU) 2016/679 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 27 April 2016 on the protection of individuals 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).

On that basis, the 'algemene verordening gegevensbescherming (AVG)' or General Data Protection Regulation was established. The AVG and the Law of 30 July 2018 (30 JULY 2018 — The Natural Protection Act for the processing of personal data) provide for increased protection in the use and processing of sensitive personal data.

The administrative authority responsible for the control and correct application of the GDPR in Belgium is the Data Protection Authority (GBA). As a result of the Law of 3 December 2017 establishing it, the GBA will replace the Commission for the Protection of Privacy with effect from 25 May 2018. It can carry out audits and is given sanctions and repressive power.

The special categories of personal data in Article 9.1 of the AVG are prohibited in principle. Nevertheless, article 9.2 of the AVG provides for a number of exceptions to this prohibition, or certain situations in which the processing of such sensitive data is permitted.

Automated individual decision-making (including profiling) cannot be based on the particular categories of personal data referred to in Article 9.1 of AVG, unless the data subject has expressly agreed to it or is required to do so by or under the law for reasons of serious public interest.

The Gegevens beschermingsautoriteit or Data Protection Authority (3 DECEMBER 2017. - Data Protection Authority Act (Publication: 10-01-2018 - Entry into force: 25-05-2018) - Text updating until 05-09-2018) is an independent body that ensures that the

fundamental principles of personal data protection are properly observed. The Data Protection Authority was established by the Belgian Federal Chamber of Deputies by Law of 3 December 2017 establishing the Data Protection Authority and is the successor to the former Privacy Commission.

Important addition:

The Minister of Social Affairs and Health, and of Asylum and Migration (hereinafter the Minister) is requesting the position of the Data Protection Authority (gba) on a number of issues relating to the processing of personal data on health, in particular: - primary processing of data from the patient record and, in particular, data sharing between healthcare practitioners (artt. 36 to 40 of the Law of 22 April 2019 on quality practice in health care) - secondary processing of data from the patient file for scientific research and public health ¬objectives with a view ¬to evaluating the quality of care; - processing of health data in the context of clinical trials.

Romania

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 ReMember – Me 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)

CHAPTER II: 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".

CHAPTER III: 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.

Ethical approval for field trials

This section contains information about the national procedures and regulations related to conducting research and field trials in the four pilot countries.

Cyprus

Field trials in Cyprus will be led by the project coordinator MATERIA. The Bioethics (Establishment and Function of the National Committee) Law of 2001 defines the National Bioethics Committee as:

'the responsible independent body whose mission is the constant monitoring, survey, systematic analysis and evaluation of the issues and problems that relate to the scientific research, progress and implementation of the sciences of biotechnology, biology, medicine, genetics and pharmaceutics as well as to the human intervention on the biological procedure and the human genotype and the investigation of their moral, deontological, social, humanistic and legal dimensions'

(L. 150(I)/2001 - The Bioethics (Establishment and Function of the National Committee) Law of 2001, 2001)

All Cypriot organisations participating in any sort of study or project that involves the aforementioned topics, ought to apply for Bioethical approval. All applicants should fill in the appropriate application forms and provide all the available information regarding the project or study that they are planning to participate in. These documents include a detailed consent form, the application form, the CVs of the project team, the approved project proposal and any supportive documents referred to in the application forms.

The CNBC processes the application form and informs the applicant whether their project is approved or not. If they found appropriate, they provide guidance,

recommendations or request further information to the applicant in order to finalise their decision.

Even after the Bioethical approval the applicant is required to provide frequent updates of the project to the CNBC in order to ensure all methods, tools and procedures are following all the dimensions the CNBC represents. Also, the applicant is required to use the approved consent forms by CNBC in all the end-user involvement phases during the project.

MATERIA has already followed these procedures and received the CNBC approval on the 7th of May 2020. As it was described above, MATERIA is going to continue to provide frequent updates to the CNBC according to the project phase.

Romania

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.

Short description of Research Ethics Committees' system in Romania:

National Committee of Medicines and Medical Devices (hereafter NCMMD):

In Romania NCMMD is one of the main institutions responsible for the ethical review of a clinical trial or for an investigational medicinal product. Its mission is to ensure that biomedical research is conducted ethically and it intervenes in the research process (before, during and after a research is approved, and also when the research results are evaluated and reported), to protect life, dignity, health, rights, comfort and safety of a clinical trial. This committee is mainly responsible for biomedical research, including research on biological materials or studies on surgical interventions, however, other non-biomedical research can be revised upon request.

National Agency for Medicines and Medical Devices (hereafter NAMMD):

The other main institution is NAMMD that also provides procedure steps for assessment and approval of applications for clinical trials with human medicine. This committee is mainly responsible for the review of clinical trials on medicinal products.

NAMMD is a public institution subordinate to the Ministry of Health, whose first mission is to protect and promote public health. The most important strategic objective of the NAMMD is promotion and protection of public health, by the accomplishment of the NAMMD primary role, namely warranty of compliance of authorized medicinal products with the required standards and intended purpose as well as of their acceptable level of safety.

National Ethics Council (hereafter NEC):

Regarding the coordination and monitoring of the application of the norms of moral and professional conduct in research and development activities, there is also the NEC that has a consultative body status.

Institutional Ethics Committees (hereafter 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.

The procedures relevant in the context of ReMember – Me project:

The Institutional Ethics Committees (hereafter IECs) have only a consultative status regarding bio-medical research. Concerning non-biomedical research, the IECs decide for the research activity from their own institutions, meaning that they review and issue approvals for these research activities.

The National Agency for Medicines and Medical Devices: The research application may be submitted to the National Agency for Medicines and Medical Devices.

To approve conduct of the clinical investigation procedure for medical devices, the manufacturer or their authorised representative shall submit an application to the NAMMD (Annex no. 1 of Order of the Minister of Health no. 792/2006). In accordance with legislation on medical devices, conduct of clinical investigations using devices authorized to bear the CE marking does not require authorisation, unless the purpose of such investigations is to use the devices for purposes other than those mentioned in the compliance assessment procedure.

Italy

Brief description of the Ethics Committee (hereafter EC) operating at Fondazione Santa Lucia IRCCS (FSL)

The EC is a multidisciplinary and independent organisation appointed by the Foundation's Management whose 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 the Committee to evaluate studies and trials for which an application is made. In particular, the subject of evaluation are activities with connotations of research and clinical trials, conducted within the

framework of the Foundation's scientific programme, in relation to its biomedical interests, pertaining to neuroscience and neuromotor rehabilitation, clinical-pharmacological research and trial protocols sponsored by public and private organisations and observational studies.

The EC's task 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, information to the physicians and healthcare professionals involved, adherence to what has been approved by the EC for the execution of examinations, the economic commitment and methods of product management related to trials.

The EC may maintain direct contact with ongoing testing activities, monitoring their performance and the adherence to clinical-care standards, and periodically reviewing them with a timeline related to the duration of studies. In case of monocentric trials, the EC must express an opinion within sixty days from the receipt of the complete request. In case of multi-centre trials in which the FSL Ethics Committee is the monitoring organisation to which the experimenter of a participating centre refers to, the Commission may communicate to the Ethics Committee of the Coordinating Centre any comments on the Protocol within 30 days from the application submission. In any case, the opinion is expressed within 30 days after receiving the opinion from the Ethics Committee of the Coordinating Centre. The EC has competence to judge all aspects of the protocol underlying a request. Moreover, if the FSL

EC is the monitoring organisation to which the experimenter of the Coordinating Centre refers to, the EC may request any amendments and/or additions to the whole protocol before the opinion is delivered, while if the FSL EC is the monitoring organisation to which the experimenter of a participating centre refers to, in addition to any considerations to be sent to the Ethics Committee of the Coordinating Centre, the EC can only accept or refuse the favorable opinion of the Centre as a whole, being able, in any event, to request any change in the informed consent only to the subjects being tested at the center to which it refers.

Decisions are taken by the majority of those present during the commission's meeting by means of an open vote by the right holders. In the event of a tie, the President's vote shall prevail. The EC gives a favorable or unfavorable judgement. The EC may withdraw its favorable opinion on the ongoing trial by reasoned decision. The submitted project may be resubmitted only once following a suspension of the Committee's opinion. If comments are not properly addressed in the second submission, the project is rejected. The opinion expressed by the EC on submitted studies is transmitted by the Secretariat to the Sponsor/Researcher and to the Presidency of FSL, for the adoption of the consequent deliberative measure.

The Authorization Measure of the President must be communicated not only to the EC, but also to the Directorates and competent departments. Researchers may not begin testing until such authorization has been received and will communicate the trial's start date to the EC.

Belgium

This section concerns research in Belgium which involves processing of personal data, regardless of the method used (e.g. interviews, questionnaires, direct online retrieval, secondary use of personal data etc.). For the aspect 'personal data collection', the paragraphs on 'Human beings' may also apply.

'Personal data' means information relating to an identified or identifiable natural living person. An identifiable natural person is one who can be identified, directly or indirectly, by reference of an identifier such as a name, an identification number, location data, an online identifier or by one or more factors specific to the physical, physiological, genetic, mental, economic, cultural or social identity of that natural person [see EU General Data Protection Regulation (GDPR), article 4]. Individuals are not considered 'identifiable' if identifying them requires excessive effort or resources. Consequently, completely anonymised data does not fall under the data privacy rules (as from the moment the data has been completely anonymised – the handling of anonymisation itself still falls under the scope of the GDPR). Personal data may come from or be used in any type of research activity (ICT research, genetic sample collection, tissue storage, personal records (financial, criminal, education, etc.) or source (lifestyle and health information, family histories, physical characteristics, gender and ethnic background, location tracking, domicile information, etc.). 'Processing of personal data' means any operation (or set of operations) performed on personal data, either manually or by automatic means, even if interviewees, human volunteers, patients, etc. are not actively included in the research.

This includes:

- collection (digital audio recording, digital video caption, etc.)
- recording
- organisation, structuring & storage (cloud, LAN or WAN servers)
- adaptation or alteration (merging sets, amplification, etc.)
- retrieval & consultation
- use
- disclosure by transmission, dissemination or otherwise making available (share, exchange, transfer)

● alignment or combination

● restriction, erasure or destruction.

The following list of personal data is considered 'sensitive' and is subject to specific processing conditions: personal data revealing racial or ethnic origin, political opinions, religious or philosophical beliefs; trade-union membership; genetic data, biometric data processed solely to identify a human being; health-related data; data concerning a person's sex life or sexual orientation (Article 4(13), (14) and (15) and Article 9 and Recitals (51) to (56) GDPR).

What is requested? Research involving personal data and confidential information must comply with institutional policies and applicable EU and national law, in particular the General Data Protection Regulation (GDPR) / Algemene Verordening Gegevensbescherming (AVG), the national data protection laws and other applicable legislation such as e.g. in case of clinical trials). Both data collection and data processing may possibly be subject to ethical authorisation as well. Processing personal data in research projects is highly context-dependent and requirements for ethical advice and (centralized) procedures for registration of personal data gathering and processing diverge amongst research institutes.

To ensure the research is in conformity with the institutional policy, we consulted the data protection office (DPO) and excluded the bedsensor in the REMEMBER-ME project because of the use of a medical registered device. For the Zora robot and the Fitbit Inspire 2, since we adequately anonymize and/or pseudonymize the data SJB can execute the research without an approval from the ethical commission, SJB will still need to evaluate and to monitor closely each data collection by the data protection office manager of Integro VZW.

References and background documents and/or further reading (non-exhaustive) Belgian legislation

● Law of 30 July 2018 on the protection of natural persons with regard to the processing of personal data

● 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) Other guidelines

● VLIR : Research Data Management en de Vlaamse Universiteiten:White Paper

● Guide on good data protection practice in research

Information letter

Prior to participation in the field trials of ReMember- Me, potential participants will be given an information letter and an explicit consent form. The aim of the information letter is to

provide all the necessary information about the study in order to guarantee that the participant has enough information about the nature of the study and their involvement in it. Thus, s/he can make an informed and adequate decision about her/ his participation in it. The information letter will give information about the following:

- Full name of the project and project number;
- Information about the ReMember – Me Consortium i.e., names of the project coordinator and partner organisations;
- Short project description - purpose of the project, project's phases, project objectives;
- Duration of field trials;
- Types of personal data that will be collected during the study;
- How the data will be collected i.e., testing procedures, devices, scales and tests that will be conducted;
- Purpose of personal data collection – Explanation about what the collected data will be used for and why it will be collected;
- Rights of participants;
- Explanation of what participation in the study would mean for volunteers;
- Possible risks, discomforts or inconveniences for study participants.

All end-users partners will use an information letter and informed consent.The Information letter that will be used for the field trials in Romania and Belgium can be seen in Annex 1. This information letter might be subject to future amendments due to the fact that the ReMember- Me system is under development. Information letters and consent forms that will be used in Italy and Cyprus can be seen in Annex 3 and Annex 4.

Explicit consent

Consent is one of the six lawful bases to process personal data, as described in Article 6 of the GDPR. Consent is considered as lawful ground for processing only if data subjects have control over their genuine choice of whether to accept or decline the terms offered by the data controller without any detriment if they decline them. That is, any inappropriate pressure or influence upon the data subject which can be manifested in many different ways which preclude a data subject from exercising their free will makes the consent invalid. According to Article 4 (11) of the GDPR consent is:

'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'

There are two types of consent – informed and explicit. As stated by Article 29 Working Party Guidelines on consent, there are several minimum requirements for consent to be informed. The following information needs to be given to data subjects in order to obtain valid consent:

- the controller's identity,
- the purpose of each of the processing operations for which consent is sought
- what (type of) data will be collected and used,
- the existence of the right to withdraw consent,
- information about the use of the data for automated decision-making in accordance with Article 22 (2)(c)34 where relevant, and
- on the possible risks of data transfers due to absence of an adequacy decision and of appropriate safeguards as described in Article 46.

To put it simply, a data controller must ensure that data subjects are fully and well-informed about who the controller is as well as understand what they are agreeing to and what the purpose for data processing is. Consent should be written in plain and clear language in order to be easily understandable by the average person and not only by lawyers. Data subjects must be given all the information that is needed for making informed decisions on whether to give their consent or not. As defined in Article 7, data subjects have the right to withdraw their consent at any time. Withdrawal of consent must not affect the lawfulness of processing based on consent before its withdrawal. Consent should be obtained before the controller begins processing personal data for which consent is required.

As stated in Article 9, explicit consent is needed when processing special categories of data such as data concerning health. The term explicit is related to the way consent is expressed by the data subject. That is, the data subject must give an express statement of consent.

The explicit consent that will be used for the pilot testing of ReMember – Me in Romania and Belgium is available in Annex 2.

The approved consent forms by the National Bioethics Committees that will be used for the pilot trials in Italy and Cyprus are available in Annex 3 and Annex 4. All consents that will be used by the partners will contain the information mentioned in this section.

Ethical guidelines for pilot testing

Pilot testing will be done in four countries namely Cyprus, Romania, Italy and Belgium. End user organisations will follow the same protocol. Whenever a project partner wants to recruit volunteers and gather their input for the ReMember – Me project in an offline context, the following steps will be followed:

People that are interested in participation in the ReMember – Me project will be informed in detail. That is, they will be given the information letter, privacy policy and consent form for review and completion before beginning personal data processing activities.

The project partner must answer clearly and adequately address all questions that a participant may have regarding the project, the information letter, privacy policy, consent form and their involvement in it.

The project partner must confirm that the participant has filled in the last section of the consent form with its name, surname, signature and date.

The project partner must check if the participant has ticked all the “Yes”- boxes in the consent form. In case the participant has not ticked “Yes” for each box, then do not proceed with the personal data processing activities.

The project partner must give the participant a copy of the information letter, privacy policy, and the signed consent form.

The project partner must provide upon a participant’s request a copy of the input they have provided.

The project partner must keep the information letter, privacy policy and consent form completed by the participant as hard copy in a file and a scanned copy saved on a secured PC connected to a secured server.

All three documents (information letter, privacy policy, consent form) must be stored during the entire duration of the data processing for which the consent was sought. Once this retention is not necessary for the purpose for which the consent was sought, documents should be stored in accordance with the retention requirements described in the applicable national legislation and/ or for the establishment, exercise or defence of legal claims.

Withdrawal or discontinuation of primary end users from the pilot trials

Throughout the pilot trials, it will be clear to voluntary participants that they have the right to withdraw their participation and their personal data at any time. ReMember - Me researchers retain the right to request a participant to be no longer involved in the study only if an acquired condition constitutes them ineligible according to the exclusion criteria and/or their participation is wrong, risky or immoral, even if the participant wishes to continue to the study. This condition may include but is not limited to, a severe/acute illness or injury, a significant decline in motor or cognitive ability, an acute acquired neurological impairment e.g. a stroke or loss of vision.

Researchers’ main goal upon making this decision will be to maintain a balance among the need to safeguard a participant and protect them from any procedure deemed risky

for them but at the same time, avoid causing any discomfort to them as a result of excluding them from the study. This is the reason that the researchers will follow a specific exit strategy for the participants excluded not by their own choice which will include:

a) detailed explanation of the reason they are asked to stop their participation to the study,

b) provision of free exercise sheets, games and material in order for them to continue their training lasting at least for the total remaining time they would be asked to participate to the ReMember-Me study if they were not excluded and

c) a list of similar products available in the market in case they wish to continue their training.

Those primary end users that are withdrawn from the study due to non-compliance will be asked to provide feedback to the researchers regarding the pilot trial and what they thought led to their lower-than-expected motivation and lower levels of compliance with the intervention. Personal data that has been collected up to the point of withdrawal will be included in subsequent analyses, unless the participant requests that their data is removed from the dataset.

Security enforcement within the project

Security and privacy requirements for ReMember-Me

This section presents security and privacy requirements that need to be implemented in the ReMember-Me system, to comply with regulations and standards regarding the collection and processing of personal data.

In general, electronic personal data is properly secured if the following conditions are met in a continuous manner:

the data accessibility is guaranteed only to authorized persons,

the data is protected against accidental or unauthorized destruction.

In such a case, the concept of secure processing of electronic medical records should be identified with the concept of 'information security' used in the field of ICT security. According to ISO/IEC 27001 standard , information security should be understood as maintaining confidentiality, integrity, availability, accountability, authenticity, non-repudiation and reliability. These terms are explained below:

confidentiality – ensuring that the data is not shared or disclosed to unauthorized persons, entities or processes;

integrity – ensuring that the data has not been altered or destroyed in an unauthorized manner;

accessibility – ensuring that the data is accessible and usable on demand, at the assumed time, by an authorized entity; In a format that it can be transportable into other systems like in a CSV (comma-separated values) format

accountability – ensuring that the entity's activities can be unambiguously assigned only to that entity;

authenticity – ensuring that the identity of the entity or resource is as declared (authenticity applies to users, processes, systems and information);

non-repudiation – the inability to deny its participation in all or part of the data exchange by one of the entities participating in this exchange;

reliability – ensuring consistency and intended behaviour and effects.

It should be noted that ensuring and then demonstrating certain properties often requires the use of specific means and simultaneous fulfilment of many conditions.

Taking into account the state of technical knowledge, the cost of implementation as well as the nature, scope and purposes of data processing, and also the risk of violation of the rights of data subjects with different probability and severity of threats resulting from data processing, the project should implement appropriate technical and organizational measures, such as anonymisation (Req#1). These measures should be designed to effectively implement data protection principles, such as data minimization, and to give processing the necessary safeguards to meet the requirements of the GDPR and protect the rights of data subjects.

An important aspect and expectation regarding anonymization is that the connection can no longer be restored, i.e., the natural person can no longer be identified.

In the case of the ReMember-Me project, a critical area of security is the servers where the solutions will be deployed. It is recommended that the developed services and database systems be stored on cloud-based servers.

The network architecture should consider implementing mechanisms of comprehensive network protection against intrusion. It is recommended to use at least the following protection mechanisms (Req#2):

- IPS (Intrusion Prevention System),
- the firewall,
- network antivirus filter.

In addition, devices on which the software for processing and storing data within the ReMember-Me system will be run, should be provided with physical and logical protection of remote diagnostic and devices' configuration ports (Req#3).

The ReMember-Me system should be placed in a secure area (Secured Zone) excluding the necessary communication modules located in the DMZ, enabling data exchange with ReMember-Me Kits. In the case of communication via an external network, strong mechanisms are required to guarantee the protection of transmitted data, their integrity, confidentiality and non-repudiation (using, for example, the SSL 3.0 / TLS 1.2 protocols) (Req#4).

In the case of securing network services, authorization procedures should be implemented specifying who is authorized to access the network and network services - access to services should be possible only for authorized users/devices by providing authentication and authorization mechanisms (Req#5).

With regard to the security of applications that constitute the ReMember-Me system, access to individual applications must require a user ID and authentication (password, authentication certificate) (Req#6). The application functionality available to individual users should be limited by the user's rights (Req#7). Sessions of system users should be blocked after a configured period of inactivity (Req#8). The system architecture should include solutions that eliminate or significantly reduce the system's vulnerability to attacks, as recommended in the Open Web Application Security Project - OWASP Top 10. Some of them can be implemented at the application level by using secure tools, libraries and algorithms (Req#9).

When a client-server application is used, it is required to provide communication security, e.g., by using the SSL (HTTPS) protocol (Req#10). In addition, it is recommended to conduct security tests of the ReMember-Me system in accordance with current guidelines, e.g., OWASP for web applications (Req#11). Moreover, the environment in which the platform will be installed should have the latest security updates (Req#12) - this applies to operating systems, web / application servers, databases, etc.

Ensuring the security and confidentiality of data in the ReMember-Me system requires the implementation of appropriate mechanisms to manage permissions and access control to data and/or functions (Req#13). Access control should in particular fulfill the following tasks and have the following functionalities:

- access to applications or data is only possible after the authentication process (Req#13.1);
- user rights should be granted to the minimum possible extent (Req#13.2);
- the system administrator grants rights, based on the application approved by the person representing the Project Partner (Req#13.3);
- access passwords must be strong enough (at least 8 characters, contain uppercase and lowercase letters and numbers or special characters) (Req#13.4);
- the password can’t be sent in plain text (Req#13.5).

- No copy pasting (ctrl c command ctrl v command) of the password must be allowed

Explicit Consent Form

As it is described in Chapter II, Section 5, collecting and processing personal data, according to the GDPR, requires prior consent from a user (Req#14). This consent applies to participation in field trials (when the primary end user is monitored using the entire ReMember-Me system), as well as to the testing of a single component (Smartwatch, Bed sensor, James robot etc.), to ensure that primary end users' data processing is legal and that the service is properly regulated. Templates of the consent forms prepared for ReMember-Me field trials are presented in Annex 1, Annex 3 and Annex 4.

Personal Data Processing Activities Register

According to the Article 30 of GDPR, we need to keep an internal record with the information of all personal data processing activities carried out within the project (Req#15).

The following information will be included in the record:

- the administrator's name and contact details (employee of end-user partners involved in the ReMember-Me project) as well as Data Protection Officer of end-user partners.
- The purposes of processing (conducting research for the needs of the ReMember-Me project).
- Description of the categories of data subjects and the category of personal data (the data related to physical and mental health of monitored persons - older adult; personal information which includes both medical and administrative data);
- categories of recipients to whom personal data will be disclosed (members of the project international consortium: research institutes, universities and companies involved in the implementation of the ReMember-Me system);
- planned dates for the deletion of personal data (the data will be removed after the end of the project, unless the consortium undertakes new activities to continue the research);
- a general description of the technical and organizational security measures of the ReMember-Me platform.

Security and privacy mechanisms and techniques considered for the ReMember-Me system

Solutions for anonymity, data integrity, and security for transfer and data access in order to address the issues related to personal data collection

Among the arsenal of IT security techniques available, pseudonymisation or anonymisation is highly recommended by the GDPR regulation. Such techniques reduce risk and assist “data processors” in fulfilling their data compliance regulations. If it can be proven that the true identity of the individual cannot be derived from anonymised data, then this data is exempt from other methods ensuring the strict confidentiality of the actual data. The two techniques differ and in face of the GDPR the choice will depend on the degree of risk and how the data will be processed.

In the ReMember-Me project data anonymisation will be used.

Anonymisation

“Anonymisation” of data means processing it with the aim of irreversibly preventing the identification of the individual to whom it relates. Data can be considered anonymised when it does not allow identification of the individuals to whom it relates, and it is not possible that any individual could be identified from the data by any further processing of that data or by processing it together with other information which is available or likely to be available.

Anonymization is not a single technique, but rather a collection of approaches, tools, and algorithms that can be applied to different kinds of data with differing levels of effectiveness.

In the case of anonymisation, by 'identification' we mean the possibility of retrieving a person's name and/or address, but also the potential identifiability by singling out, linkability and inference.

Anonymisation techniques

The following techniques can be used to anonymize records of information:

Noise Addition: The personal identifiers are expressed imprecisely (example, weight is expressed inaccurately +/- 10 lb).

Substitution/Permutation: The personal identifiers are shuffled within a table or replaced with random values (example, a zip code of 80629 is replaced with “Magenta”).

Differential Privacy: The personal identifiers of one data set are compared against an anonymized data set held by a third party with instructions of the noise function and acceptable amount of data leakage.

Aggregation/K-Anonymity: The personal identifiers are generalized into a range or group (example, a salary of $42,000 is generalized to $35,000 - $45,000).

L-Diversity: The personal identifiers are first generalized, then each attribute within an equivalence class is made to occur at least “l” times. (example, properties are assigned to personal identifiers, and each property is made to occur with a dataset, or partition, a minimum number of times).

Hash Functions: The personal identifiers of any size are replaced with artificial codes of a fixed size (example, Paris is replaced with “01”, London is replaced with “02”, and Rome is replaced with “03”).

Tokenization: The personal identifiers are replaced with a non-sensitive identifier that traces back to the original data, but are not mathematically derived from the original data (ie, a credit card number is exchanged in a token vault with a randomly generated token “958392038”).

Security for transfer and data access

Ensuring the security of the ReMember-Me platform concerns the implementation of secure health data transmission, ensuring security for the data access and introducing security at the level of recording health data. A number of documents are available containing recommendations in the field of IT system security and guidelines in the field of medical data security, such as: NIST Cybersecurity Framework, HL7 security and privacy standards, ISO 27001 and ISO 27799, HITRUST CSF.

Analysis of the above documents has shown that in order to ensure security, at least user authentication based on passwords or certificates, data encryption, and the use of a firewall are recommended.

The recommendations described in the documents published by HITRUST Alliance indicate that valid encryption process includes:

- Transport Layer Security (TLS) 1.0;
- Secure Sockets Layer (SSL) 3.1;
- IPSec VPNs:
- Gateway-To-Gateway Architecture;
- Host-To-Gateway Architecture;
- Host-To-Host Architecture;
- SSL VPN:
- SSL portal VPN,
- SSL Tunnel VPN.

In the designed ReMember-Me solution, medical data will be transferred using the REST API. To secure data transmission, it is recommended to use the HTTPS protocol using the TLS protocol to encrypt data. This approach gives the opportunity to use three levels of data access security. The system can be available to users based on:

level 1 - Basic Access Authentication - based on login / password;

level 2 - Digest access authentication - it applies a hash function to the username and password before sending them over the network;

level 3 - Authentication using HTTPS client certificates.

Level 3 is the most secure and recommended for securing access to medical data.

Security of an access to health data can be also achieved based on the use of a firewall with appropriate security rules and involvement of an HTTP proxy server (e.g. Apache Server, Nginx server or Squid). For example, the security capabilities of the Nginx server are following:

- NGINX SSL Termination;
- Restricting Access with HTTP Basic Authentication;
- Authentication Based on Subrequest Result;
- Limiting Access to Proxied HTTP Resources;
- Restricting Access to Proxied TCP Resources;
- Securing HTTP Traffic to Upstream Servers;
- Securing TCP Traffic to Upstream Servers;
- Dynamic Blacklisting of IP Addresses.

The last issue is the secure storage for the health data. The system for storing data considered in the project is the PostgreSQL database. PostgreSQL gives the option of encryption at several levels, and provides flexibility in protecting data from disclosure due to database server theft, unscrupulous administrators, and insecure networks. The following levels of encryption usage are available:

Password Storage Encryption - database user passwords are stored as MD5 hashes;

Encryption For Specific Columns - the library pgcrypto allows certain fields to be stored encrypted; this is useful if only some of the data is sensitive: the client supplies the decryption key and the data is decrypted on the server and then sent to the client;

Data Partition Encryption - on Linux system an entire file system partition can be encrypted on disk, and decrypted by the operating system;

Encrypting Passwords Across a Network - the MD5 authentication method double-encrypts the password on the client before sending it to the server; it first MD5 encrypts

the password based on the user name, and then encrypts it based on a random salt received from the server when the database connection was made;

Encrypting Data Across A Network - SSL connections encrypt all data sent across the network: the password, the queries, and the data returned;

SSL Host Authentication - it is possible for both the client and server to provide SSL keys or certificates to each other.

Security Incident Management Plan for ReMember – Me

Data breaches are possible. Therefore, the ReMember – Me consortium has developed its Security Incident Management Plan. A personal data breach can be defined as a security incident that results in a breach of confidentiality, integrity or availability of personal data. Both the controller and the processor have certain duties when data breach occurs. In the case of ReMember - Me, there are Joint Data Controllers namely AgeCare (Cyprus) Ltd – Materia Group, Ana Aslan International Foundation, Fondazione Santa Lucia, Sint Jan Berchmanstehuis part of the Integro group and Joint Data Processors i.e. Technical University of Cluj - Napoca, ARTOFINFO Kereskedelmi es Szolgaltato Korlatolt Felelossegu Tarsasag, and ePoint BVBA.

If there is a data breach, the data controller has to notify the competent national supervisory authority or in the case of cross-border breach the lead supervisory authority within 72 hours.

Taking into account that the ReMember – Me project involves partners from several EU countries who act as joint data controllers, and the location of the project coordinator i.e. the main establishment, the lead supervisory authority will be the Office of Commissioner for Personal Data Protection in Cyprus.

In some cases, the breach has to be communicated to the data subjects i.e. the individuals whose personal data have been affected by the breach. Recital 85 of the GDPR describes this obligation as follows:

“Therefore, as soon as the controller becomes aware that a personal data breach has occurred, the controller should notify the personal data breach to the supervisory authority without undue delay and, where feasible, not later than 72 hours after having become aware of it, unless the controller is able to demonstrate, in accordance with the accountability principle, that the personal data breach is unlikely to result in a risk to the rights and freedoms of natural persons. 3Where such cannot be achieved within 72 hours, the reasons for the delay should accompany the notification and information may be provided in phases without undue further delay.”

When the supervisory authority is notified, controllers can get advice on whether the affected people need to be informed about the breach.

According to Article 33 (GDPR), the processor is obliged to notify the controller of a data breach as soon as it was detected without any unnecessary delay.

Failure to report a breach to either a data subject or a supervisory authority, may mean a possible sanction under Article 83 of the GDPR.

As described earlier, the ReMember – Me system has joint data controllers, joint data processors and cross-border processing of personal data. Cross-border processing is defined in Article 4(23) of the GDPR as either the:

processing of personal data which takes place in the context of the activities of establishments in more than one Member State of a controller or processor in the Union where the controller or processor is established in more than one Member State; or

processing of personal data which takes place in the context of the activities of a single establishment of a controller or processor in the Union but which substantially affects or is likely to substantially affect data subjects in more than one Member State.

In the event of any incident that affects the security of users' data handled in the ReMember – Me system, the Security Incident Management Plan presented in Figure 2 will be carried out.

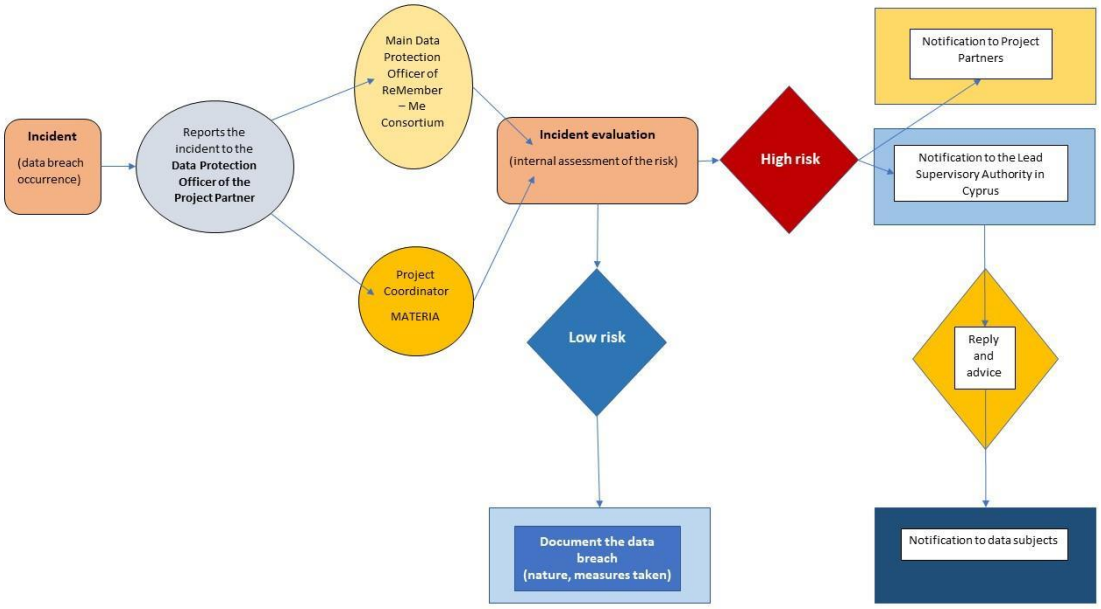

Figure 2.Security Incident Management Plan

If data breach occurs, a project partner's employee must report the incident to the main Data Protection Officer of the ReMember – Me consortium as well as the project coordinator MATERIA. Then the risk is evaluated internally by the main DPO and

MATERIA. Internal incident evaluation must identify and assess the risk by taking into consideration its type, sensitivity and volume of personal data, ease of identification of data subjects, severity of consequences for individuals, number of affected individuals etc.

In general, when the controller assesses the risk that is likely to result from a breach, the controller should consider the severity of the impact on the rights and freedoms of individuals and the likelihood of it occurring. Recital 85 of the GDPR specifies these adverse effects:

'A personal data breach may, if not addressed in an appropriate and timely manner, result in physical, material or non-material damage to natural persons such as loss of control over their personal data or limitation of their rights, discrimination, identity theft or fraud, financial loss, unauthorised reversal of pseudonymisation, damage to reputation, loss of confidentiality of personal data protected by professional secrecy or any other significant economic or social disadvantage to the natural person concerned.'

If the risk is assessed internally as high, then MATERIA must send an official notification to the Lead Supervisory Authority in Cyprus aka the Office of Commissioner for Personal Data Protection. Notification must be sent no later than 72 hours after the data breach occurred. Once the Lead Supervisory Authority is notified, it will give advice and reply on how to proceed and whether to notify data subjects or not.

When there is a personal data breach which may result in high risk to the rights and freedoms of individuals, then the controller should notify the supervisor authority. Article 33 (3) describes the minimum information that the notification must include. It is as follows:

- A description of the nature of the personal data breach 'including where possible, the categories and approximate number of data subjects concerned and the categories and approximate number of personal data records concerned;
- The name and contact details of the data protection officer or another contact person where more information about the data breach can be obtained
- A description of the likely consequences of the personal data breach
- Measures already taken and measures to mitigate the possible adverse effects of the data breach – 'describe the measures taken or proposed to be taken by the controller to address the personal data breach, including, where appropriate, measures to mitigate its possible adverse effects.'
- Article 33 (5) requires the data controller to document all facts related to the breach, its effects, and the remedial action taken.
- If the risk is assessed internally as low, then MATERIA and the main DPO of the ReMember- Me Consortium will document the data breach and keep a record

of it. That is, its nature will be described as well as the measures and actions which have been taken by project partners.

Ethics Board

The Remember – Me Consortium has designated a project Data Protection Officer (DPO), Ms Nellie Gospodinova from the Ana Aslan International Foundation. In addition to the project DPO, during the field trials, each project partner will appoint their own DPO in case they do not have one. The ReMember- Me project DPO will act as a contact point for data subjects and the lead supervisory authority in Cyprus. The project DPO will monitor internal compliance with the GDPR, will inform and provide advice on the consortium's data protection obligations.

Moreover, the ReMember – Me Consortium has its own Ethics Board as presented in Fig.3 below. It includes members with experience in ethical standards, both internal and external experts. Members of the Ethics Board give advice on ethical matters and issues especially all aspects of the dignity, autonomy and values (human and professional) of the primary and secondary end users. Furthermore, the Ethics Board observes the ethical issues concerning the relationship between all end user groups and the project, including informal carers.

Ethics Board			
Country	**Organization**	**Person**	**Status of appointment**
Cyprus	MAT	Dr Marios Kyriazis	Completed
Italy	FSL	Dr Clelia Pellicano	Completed
Romania	ANA	Pr. Luiza Spirou	Completed
Belgium	SJB	Mrs Greet Geuens	Completed

Figure 3. ReMember-Me Ethics Board

Data Management Plan

Types of data

Different types of personal data will be collected in the ReMember- Me project and system. All personal data, its source as well as purposes for collection are presented in a table in Annex 6.

The following data categories will be processed throughout the ReMember – Me project:

In the Registration process, the following of your personal data will be processed: first name, last name, gender, age, weight, height, years of education, living status, country and city of residence, email address, phone number, username, password, level of assistance needed, personal interests and experience.

In the Baseline Assessment performed on the ReMember – Me system, the following of your personal data will be processed: ReMember - Me Cognitive Assessment Scale (RMCAS), 4-item Personal Wellbeing scale, 15-item Geriatric Depression Scale (GDS), Rapid Assessment of Physical Activity (RAPA), 11-item De Jong Gierveld Loneliness Scale, motor function and activities, single item Sleep Quality scale.

In the ReMember – Me Testing and Evaluation Phase, the following of your personal data will be processed: information and results from detection exercises, results from games, rehabilitation activities, your user's activities, your frequency of system's usage, hours of usage of the system and its devices, number of registrations per category, physiological parameters measured by ReMember – Me devices like physical activity data from the fitness tracker, data from sleep analyser, any information you decide to share with us through discussions, interviews, questionnaires, correspondence, follow-up visits, as well as data providing performance, satisfaction, motivation feedback from participant's point of view.

Credentials - IP address, passwords, password hints, and similar security information used for authentication and account access.

Sources of data

Personal information will be collected from project participants, from discussions with researchers of the ReMember – Me Project, baseline assessment, usage and interaction with the ReMember – Me system, measurements of the wearable devices provided to primary end users, from interviews, questionnaires and scales such as ReMember- Me Cognitive Assessment Scale (RMCAS), 4-item Personal Wellbeing scale, 15-item Geriatric Depression Scale (GDS), Rapid Assessment of Physical Activity (RAPA), 11-item De Jong Gierveld Loneliness Scale, motor function and activities, single item Sleep Quality scale and from processed data providing performance, satisfaction, motivation.

Data storage

ReMember- Me consortium will keep personal information for as long as necessary to fulfil the purposes outlined in the Privacy Policy unless otherwise required by law and the contract's number AAL-2019-6-188-CP for ReMember – Me Project. Personal data collected through the ReMember- Me system will be stored on a cloud owned and managed by TUC and AOI.

The personal (socio-demographic) data will be collected by each of the end-user organization piloting and then pseudonymized before moving to the further testing's stage e.g. battery of cognitive tests and data gathered through the system. These data have to be securely stored on local hard drives as password protected files; the physical forms should be kept in locked, fireproof drawers.

Data retention

Personal data will be retained for the duration of the ReMember – Me Project (i.e. until 1st of April 2024) or for a shorter period as long as these data are required to fulfil the activities set out in the Information letter and the Privacy Policy. After such period, personal data may be archived, where possible in an anonymised format, in accordance with applicable legal or contractual requirements for consortium partners (the requirements of the contract's number AAL-2019-6-188-CP for ReMember – Me Project: for example 3 years after the end of the project in Romania and 5 years after the end of the project in Cyprus).

ReMember – Me project partners may also retain personal data if it is reasonably necessary to comply with any legal obligations, meet any regulatory requirements, resolve any disputes or litigation, or as otherwise needed to enforce the Privacy Policy and prevent fraud and abuse. To determine the appropriate retention period for the information collected from project participants, ReMember- Me project partners will consider the amount, nature, and sensitivity of the personal data, the potential risk of harm from unauthorised use or disclosure of the data, the purposes for which we process the personal data, and whether we can achieve those purposes through other means, and the applicable legal requirements.

Data handling procedures

Personal data collected offline by Project Partners' researchers at the four pilot sites will be handled in the following ways:

- Data will be pseudonymized – Identity of data subjects will be concealed by replacing their names with codes such as Ro – PEU – 01 for example;
- Direct data identifiers will be kept separate from the data set - Codes will be kept locked in a safe;
- Key to the codes will be known only by authorised members of the Project Partners' research teams;
- All data that is included in internal reports, tables, internal communications, public deliverables will be anonymized and will not contain identifiable details;
- Access to pseudonymized data will be given only to authorised researchers at the four pilot sites;
- Any questionnaires or input acquired from voluntary participants in the scope of the ReMember-Me project will be handled in the strictest confidence;
- Paper questionnaires will be kept in a folder which is kept in a lockable drawer;
- Computer files containing data will be saved on secured server and network;
- Computers on which data is stored will be in a locked room (when the room is not in use by research staff).

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Annexes

Annex 1: Information Letter for participation in the ReMember-Me project

Information letter

This information letter provides information about the ReMember – Me Project to people who are interested in contributing and providing input to the project. It contains information on what the project is about and what participation will mean for you.

About the ReMember – Me Project

1.1. Full name of the project:

Smart assistant to prevent and detect cognitive decline, promote cognitive function and social inclusion among older adults

Acronym: ReMember – Me

(hereafter the ”ReMember – Me Project”)

Project No: AAL-2019-6-188-CP

Here is some more information about the ReMember – Me project (https://www.rememberme-aal.eu/).

For any information about your rights as a participant in the testing phases or if you have any question, you can contact the research contact person at the address given below (CONTACT PERSONS).

1.2. Funding:

This project was supported by a grant of the Romanian National Authority for Scientific Research and Innovation, CCCDI – UEFISCDI and of the AAL Programme with co-funding from the European Union’s Horizon 2020 research and innovation programme project number AAL-2019-6-188-CP within PNCDI III.

1.3. Project partners

Who is responsible for the project?

The ReMember-Me consortium is responsible for the project implementation. The consortium consists of eight partner organisations located in six countries.

Project Coordinator: AgeCare (Cyprus) Ltd – Materia Group - Cyprus

Technical University of Cluj – Napoca - Romania

Ana Aslan International Foundation – Romania

IRCCS Fondazione Santa Lucia – Italy

ESKILARA S. Koop. Txikia – Spain

ARTOFINFO Kereskedelmi es Szolgaltato Korlatolt Felelossegu Tarsasag – Hungary

ePoint BVBA – Belgium

Sint Jan Berchmanstehuis part of the Integro group – Belgium

1.4. Project objectives

What are the aims of the ReMember – Me Project?

ReMember – Me is a multinational project funded by the Active Assisted Living Joint Programme that aims to detect and prevent cognitive decline early on in older adults. Cognitive decline or cognitive impairment is defined as a state in which a person has difficulties in remembering, concentrating, learning new things, or making decisions which affect their everyday life. Cognitive decline ranges from mild to severe (major). When people have mild cognitive impairment (or else Mild Neurocognitive Disorder- hereafter Mild NCD), they have difficulties in at least one of the cognitive domains mentioned above (e.g., remembering, concentrating, etc.) but these difficulties do not affect significantly their ability to do everyday activities independently (e.g., paying bills or taking medication). When people have severe cognitive impairment (or else Major NCD) they have significant difficulties in at least one of the cognitive domains mentioned above (e.g., remembering, concentrating, etc.) and these difficulties hinder their ability to do everyday activities independently (e.g., they need help to pay bills or take their medication). Early on diagnosis of cognitive decline (Mild Cognitive Impairment (MCI) state or before Mild Cognitive Impairment is manifested) is very important. Being diagnosed early on with cognitive decline gives a person a chance for improvement or maintenance of their cognitive functioning through stimulating activities and counteractive actions.

ReMember – Me is a smart system that integrates feedback from a social robot, tablet, fitness tracker and sleep analyser. It offers baseline assessment for cognitive impairment, detection exercises, stimulating games, and socializing through its Meet people social platform.

Project participation

Why are you asked to participate?

Your voluntary participation in the ReMember – Me Project is very important for the advancement of research in the field of cognitive decline prevention. Your contribution to this study will be for research purposes only. Data gathered during the testing will help the ReMember- Me consortium to:

Validate the ReMember – Me system

Adapt its features to the needs of older adults and improve them

Monitor the system's effectiveness and take appropriate measures to make it better

We hope that your involvement into a multinational research project aiming at improving the quality of life and independent functioning of seniors at their own home may represent a moral reward for you.

What does it mean for you to participate in the ReMember – Me Project?

Field trials of ReMember – Me will be conducted in four countries namely Cyprus, Italy, Romania and Belgium. The system will be tested by older adults who are over 65 years-old, living at home. Research participants will be cognitively intact and with Mild Cognitive Impairment. They can have mobility issues.

Study participants will test the ReMember – Me system for eight consecutive weeks in their home environment. Testing of the system will involve daily interactions with a social robot called James and a tablet. A fitness tracker, worn on your wrist, will monitor and record your physical activity all the time. Sleep analyser will monitor your sleep activity. The first prototype of the system will consist only of the baseline assessments. The second prototype will include detection, monitoring and individualized suggestion features.

You will be trained on how to use the ReMember – Me system and its devices by Ana Aslan International Foundation's team of researchers at your home. You will be shown how to switch on and safely use the robot, tablet, fitness tracker and sleep analyser. If you encounter any difficulties in using the devices, a researcher will assist you upon your request.

All data collected through the different devices will be shared with a family relative/ informal or formal caregiver as well as an appointed by you physician. Access to your health data will be authorized only by you and only to the persons you choose to receive your results.

About 120 voluntary participants in 4 countries are expected to take part in this study. Every study participant will receive baseline assessment. Baseline assessment will

consist of: ReMember- Me Cognitive Assessment Scale (RMCAS), 15-items Geriatric Depression Scale, 11-item De Jong Gierveld Loneliness Scale, Personal wellbeing scale, RAPA (Rapid Assessment of Physical Activity), Single-item Sleep Quality Scale.

Baseline assessments will be done on the tablet. Your cognitive condition will be assessed twice during the pilot trial. Once before you start testing the ReMember – Me system (pre-test) and after you have used it for two consecutive months (post-test).

It is desired that you use the system, play games and do recommended exercises for at least fifteen minutes a day.

You might be asked to take part in interviews or fill in some questionnaires and surveys before (pre-test) or after testing (post-test). You are free to reply to the questions you want to and give no response to the ones you do not wish to.

The personal motivation for participating in any activity of the ReMember – Me project is that you can make a substantial contribution to the development of future technologies focusing on the enhancement of the quality of life of ageing persons and supporting an independent lifestyle. In any case, the data collected in this study will lead to a deeper and better knowledge and understanding of the wishes and needs of ageing persons as well as their social environment to enhance future health services and care processes.

Participation is voluntary

Your participation in the ReMember – Me project is voluntary and you can choose to stop participating at any time. You can withdraw your consent at any time without giving any reason. It shall be as easy to withdraw as to give consent. The withdrawal of consent shall not affect the lawfulness of processing based on consent before its withdrawal. There will be no negative consequences for you if you decide to withdraw your consent. Data and information that has been collected up to the point of withdrawal will continue to be used by the ReMember – Me Consortium, unless the participant requests that their data is removed from the dataset.

If you should decide to withdraw your consent, please contact the research contact person and let her/him know of your intention of leaving the research project. You can contact the research contact person at the address given below (CONTACT PERSONS). Please keep in mind that if you do not provide us with your authorization now or if you cancel it in the future, you will not be able to participate in this study.

ReMember - Me researchers retain the right to request a participant to be no longer involved in the study only if an acquired condition constitutes them ineligible according to the exclusion criteria and/or their participation is wrong, risky or immoral, even if the participant wishes to continue to the study. This condition may include but is not

limited to, a severe/acute illness or injury, a significant decline in motor or cognitive ability, an acute acquired neurological impairment e.g. a stroke or loss of vision. Researchers' main goal upon making this decision will be to maintain a balance among the need to safeguard a participant and protect them from any procedure deemed risky for them but at the same time, avoid causing any discomfort to them as a result of excluding them from the study.

This is the reason why the researchers will follow a specific exit strategy for the participants excluded not by their own choice which will include:

a) detailed explanation of the reason they are asked to stop their participation to the study,

b) provision of free exercise sheets, games and material in order for them to continue their training lasting at least for the total remaining time they would be asked to participate to the ReMember-Me study if they were not excluded and

c) a list of similar products available in the market in case they wish to continue their training.

How do we store and handle the information you provide?

Your privacy is important to us. We respect the principles of data processing (General Data Protection Regulation (EU GDPR[1]): lawfulness, fairness, transparency, 'purpose limitation', 'data minimisation', 'accuracy', 'storage limitation', 'integrity and confidentiality', 'accountability'. Personal information will be collected from you once you register in the ReMember – Me system and start using it.

The purpose of personal data processing:

Results from this study will be used for the ReMember – Me project and for scientific purposes only. Personal data will be processed in a manner that ensures appropriate security and confidentiality of personal data, which includes preventing unauthorized access to or use of personal data and the equipment used for processing. Recorded information will be processed during the phase of data analysis and will be included in project internal reports or later in scientific publications. Your recorded information will only be processed for the purposes of the project ('purpose limitation') and limited to what is necessary in relation to the purposes for which they are processed ('data minimisation'). The results of this study may be published in scientific magazines, conference proceedings or books.

You have the right to:

information about the processing of your personal data;

obtain access to the personal data held about you;

ask for incorrect, inaccurate or incomplete personal data to be corrected;

request that personal data are erased when no longer needed or if processing it is unlawful;

object to the processing of your personal data for marketing purposes or on grounds relating to your particular situation;

request the restriction of the processing of your personal data in specific cases;

receive your personal data in a machine-readable format and send it to another controller (‘data portability’);

request that decisions based on automated processing concerning you or significantly affecting you and based on your personal data are made by natural persons, not only by computers. You also have the right in this case to express your point of view and to contest the decision.

To exercise your rights, you should contact the research contact person at the address given below (CONTACT PERSONS).

Full description of personal information collected through the ReMember – Me system and how we process it is available in our Privacy Policy (attached).

Here we present only information regarding data collected through additional surveys, interviews, questionnaires conducted by researchers.

Risks and inconveniences

It is wise not to expect to broadly and definitely improve your cognitive state as a result of participating in this project and using the system. You will be testing a prototype that may not be fully functional or have technical problems. The ReMember – Me system cannot replace an examination by your physician. However, by taking part in this study you will get new information about yourself that may help you improve your quality of life by remaining active and learning new things.

Potential disadvantages or risks of participating are kept to a minimum. However, daily interaction with a social robot, using a tablet, and wearing a fitness tracker may cause certain psychological and/or physical inconveniences and discomforts for you in the beginning of testing. Should these occur, do not hesitate to contact our researchers who will help you cope with them. You have the right to withdraw from participation at any time in the ReMember- Me Project.

CONTACT PERSONS

For further information about your rights as a participant in the testing phases, or if you are not satisfied with the way this study is being carried out, or if you have any question or complaint during the testing phase, please contact the leading researcher:

[Name, surname of researcher/s]

[End-user organization name]

[Full address of end-user organization]

[Telephone number of researcher/ s]

[Email address of researcher/s]

This document was prepared by ……. on …….

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[1] 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): https://eur-lex.europa.eu/eli/reg/2016/679/oj

Annex 2: Explicit consent form for participation in the ReMember- Me project

PROJECT NAME:

Smart assistant to prevent and detect cognitive decline, promote cognitive function and social inclusion among older adults

Acronym:

ReMember – Me

Project No: AAL-2019-6-188-CP

Funding: Project partially funded by AAL joint programme and “Research and Innovation Foundation” (CY), UEFISCDI (RO), IMoH (IT), “Bizkaia Foru Aldundia/

Diputación Foral de Bizkaia" (ES), National Research, Development and Innovation Office (HU) and "Vlaio" (BE) under the

Grant Agreement number AAI- 2019-6- 188- CP

Consent Form - Annex to Information letter

There are twenty-four sections in this form. Each section has a statement and asks you to check if you agree. The end of this form is for the researchers to complete.

Please ask any questions you may have when reading each of the statements.

Please Check the box if you agree with the statement. Please feel free to ask questions if there is something you do not understand.

Thank you for participating!

General		
I confirm I have read and understood the Information Letter and Privacy Policy (attached) for the above project. The information has been fully explained to me and I have been able to ask questions, all of which have been answered to my satisfaction.	Yes ☐	No ☐
I give my consent to participate in the two pilot trials of the research project entitled ReMember – Me: Smart assistant to prevent and detect cognitive decline, promote cognitive function and social inclusion among older adults.	Yes ☐	No ☐
I understand that this project is entirely voluntary and if I decide that I do not want to take part, I can stop taking part in this project at any time without giving a reason. I understand that deciding not to take part will have no negative consequences for me.	Yes ☐	No ☐
I understand that participation may involve being interviewed and tested by researchers, members of the ReMember – Me Project, and doctors.	Yes ☐	No ☐
I understand that my results from baseline assessments conducted on the ReMember – Me platform will be accessible and visible to the family relative/ caregiver and physician appointed by me. I agree that authorised by me individuals such as a relative/ caregiver and physician can access my records. I understand that I can revoke the access rights for these people whenever I want, without giving any explanations and without any consequences.	Yes ☐	No ☐

I understand that my results from detection exercises conducted on the ReMember – Me platform will be accessible and visible to the family relative/ caregiver and physician appointed by me. I agree that authorised by me individuals such as a relative/ caregiver and physician can access my records. I understand that I can revoke the access rights for these people whenever I want, without giving any explanations and without any consequences.	Yes ☐	No ☐
I understand that my performance and results from playing games on the ReMember – Me platform will be accessible and visible to the family relative/ caregiver and physician appointed by me. I agree that authorised by me individuals such as a relative/ caregiver and physician can access my records. I understand that I can revoke the access rights for these people whenever I want, without giving any explanations and without any consequences.	Yes ☐	No ☐
I understand that I will not be paid or receive any materialistic reward for taking part in this project.	Yes ☐	No ☐
I know who to contact if I have any question about the ReMember- Me project, my participation thereto or my privacy.	Yes ☐	No ☐
I consent to take part in this project having been fully informed of the risks, inconveniences and benefits which are described in full in the Information Letter which I have been provided with.	Yes ☐	No ☐
I agree to being contacted by researchers by email and phone as part of this project.	Yes ☐	No ☐
I agree that my data is collected in a central database. In order to facilitate scientific discoveries, my non-identifiable data will be made available to the public (in absolutely anonymous form) for the use permitted by research.	Yes ☐	No ☐
Data processing		

I consent to the collection of personal data such as my name, email address, country and city of residence, phone number, gender, years of education, living status, technology literacy in accordance with the purposes of this research project.	Yes ☐	No ☐
I understand that personal information about me, including the transfer of this personal information about me outside of the EU, will be protected in accordance with the General Data Protection Regulation.	Yes ☐	No ☐
I consent to the collection of data about me from the ReMember-Me Cognitive Assessment Scale conducted on the ReMember – Me platform.	Yes ☐	No ☐
I consent to the collection of data about me from the Geriatric Depression Scale conducted on the ReMember – Me platform.	Yes ☐	No ☐
I consent to the collection of data about me from the Personal wellbeing scale conducted on the ReMember – Me platform.	Yes ☐	No ☐
I consent to the collection of data about me related to my sleeping activity.	Yes ☐	No ☐
I consent to the collection of data about me related to my physical activity.	Yes ☐	No ☐
I give permission for results from my baseline assessments to be used in this project.	Yes ☐	No ☐
I give permission for results from rehabilitation games to be used in this project.	Yes ☐	No ☐
I give permission for results from detection exercises to be used in this project.	Yes ☐	No ☐
I consent to the collection of information about my weight and height.	Yes ☐	No ☐
I have been given a copy of the Information Letter, Privacy Policy and this consent form.	Yes ☐	No ☐

Participant Name Signature:
Date: ……..

Witness Name Signature:
Date: ……..

To be completed by the Principal Researcher

I, the undersigned, have taken the time to fully explain to the above participant the nature and purpose of this research project in a way that she/ he could understand. I have explained the risks and possible benefits involved. I have invited the participant to ask questions on any aspect of the project that concerned her/ him.

I have given a copy of the Information Letter, Privacy Policy and this Consent form to the participant with contacts of the research team.

Researcher Name

Signature

Date

Annex 3: Information letter and consent form in Italian (FSL)

Titolo Progetto: ReMember-Me

FOGLIO INFORMATIVO E MODULO DI CONSENSO PER IL PARTECIPANTE

La Fondazione Santa Lucia è un Istituto di Ricovero e Cura riconosciuto a Carattere Scientifico, che svolge, insieme all'attività di assistenza, quella di ricerca sanitaria e di formazione nel settore della riabilitazione neuromotoria e delle neuroscienze.
Nell'ambito di tale esercizio, è in corso una ricerca dal titolo: ReMember-Me: Smart assistant to prevent and detect cogniive decline, promote cognitive function and social inclusion among older adults.

1. INFORMAZIONI GENERALI

Per partecipare al nostro progetto di ricerca "ReMember-Me", è necessario che Lei acconsenta ai termini e alle condizioni descritte nel seguente modulo di consenso informato. Lo legga attentamente prima di apporre la sua firma. È importante che comprenda pienamente cosa implica la Sua partecipazione in modo da essere pienamente consapevole; per questo si prenda il tempo necessario per leggerlo. Qualora lo ritenesse necessario può confrontarsi liberamente con i suoi parenti, amici o consulenti prima di firmare. Se ha delle domande, non esiti a porLe al nostro staff in qualsiasi momento.

Capo Progetto: Marina Polycarpou, Agecare (Cyprus) Ltd – Materia Group
Consorzi partecipanti: Università Tecnica di Cluj-Napoca (Romania), Fundatja Ana Aslan International (Romania), Sint-Jan Berchmans (Belgio), Eskilara S. Koop. Txikia (Spagna), Artofinfo (Ungheria), ePoint BVBA (Belgio)

2. OBIETTIVI DELLO STUDIO

Lo scopo dello studio è di verificare l'efficacia di un sistema intelligente che offre un paradigma innovativo prendendo in considerazione la cognizione, il benessere emotivo, i pattern sonno/veglia e la socializzazione, promuovendo le interazioni sociali nel contesto e offrendo suggerimenti individualizzati per un cervello sano.

L'obiettivo principale del sistema è di individuare e prevenire in fase precoce il declino cognitivo, non soltanto in adulti sani, ma anche in pazienti affetti da Mild Cognitive Impairment (MCI).

ReMember-Me ha lo scopo di agire su 3 livelli principali: (i) Offrire un monitoraggio; (ii) Individuazione e training cognitivi personalizzati; (iii) Essere integrabile nei modelli di vita quotidiana degli adulti più anziani.

Questo progetto è cofinanziato dall'Active and Assisted Living Programme (AAL-2020) [numero progetto: AAL-2019-6-188 CP].

3. PROCEDURA E METODOLOGIA

Il progetto "ReMember-Me" offre un sistema intelligente costituito da un robot sociale ed un tablet che viene utilizzato per monitore e valutare il declino cognitivo. Inoltre, attraverso l'utilizzo di una serie di sensori, il sistema acquisirà quotidianamente la valutazione del sonno, delle attività, dell'umore e dell'orientamento nel tempo. Verranno suggeriti degli esercizi di potenziamento cognitivo interessanti e personalizzati sulla base delle loro routine e preferenze. Infine, il sistema fornirà una piattaforma di monitoraggio che collegherà gli anziani con i propri caregiver e una piattaforma sociale che li collegherà con altre persone desiderose di conoscere e apprendere dai ricordi e dalle esperienze passate degli anziani, incrementando cosi la socializzazione attraverso la condivisione delle conoscenze.

Per valutare tali dispositivi, Le chiederemo di compilare dei questionari e di partecipare a dei colloqui con gli esperti. Inoltre, prima dell'inizio dello studio e alla fine le chiederemo di effettuare una valutazione neuropsicologica e psicopatologica. Questa indagine permetterà di osservare i cambiamenti nel suo comportamento e nelle sue funzioni cognitive senza procurare nessun danno

alla sua salute: tale valutazione sarà utilizzata soltanto a scopo di ricerca e non riceverà nessun referto medico. Questi dati saranno resi anonimi prima di ulteriori utilizzi.

Nessun dato personale sarà raccolto senza il Suo consenso. Se necessario, richiederemo il consenso di un Suo rappresentante legale.

4. RISCHI ED INCOVENIENTI

La sua partecipazione a questo progetto non comporta rischi o inconvenienti alla Sua persona. Attualmente non si conoscono particolari rischi associati ai progetti di ricerca basati su dispositivi elettronici usati come supporto alle attività quotidiane. Il robot, il tablet e gli altri dispositivi sono dotati delle certificazioni necessarie per la vendita al pubblico. Le interviste utilizzate sono semplici indagini sull'accettabilità e la fruibilità, nonché procedure standard medico-psicologiche condotte da esperti.

5. BENEFICI E VANTAGGI

La partecipazione allo studio non prevede costi a Suo carico. Ci aspettiamo che questo studio aiuti ad acquisire nuove conoscenze riguardo l'utilizzo nell'ambiente domestico di sistemi intelligenti e automatizzati. In aggiunta, le persone anziane che vivono da sole saranno supportate nelle loro attività quotidiane in futuro e quindi saranno in grado di mantenere la propria indipendenza il più a lungo possibile. Il Comitato Etico locale è stato informato ed ha approvato tale studio.

6. PARTECIPAZIONE VOLONTARIA E TERMINE DELLO STUDIO

La sua partecipazione allo studio è assolutamente volontaria. Potrà revocare il suo consenso in qualsiasi momento, semplicemente avvertendo uno dei ricercatori o uno dei loro assistenti senza dare spiegazioni riguardo alla sua decisione.

7. RISERVATEZZA

In questo progetto raccoglieremo le Sue informazioni personali, tali informazioni saranno trattate ai sensi del Regolamento UE 2016/679 (di seguito GDPR) che prevede e rafforza la protezione e il trattamento dei dati personali alla luce dei principi di correttezza, liceità, trasparenza, tutela della riservatezza e dei diritti dell'interessato in merito ai propri dati.

I dai raccolti durante tutta la durata della Sua partecipazione saranno inizialmente forniti di uno pseudonimo, ovvero soltanto le persone coinvolte nello studio saranno a conoscenza dei suoi dati personali. Tali persone hanno firmato un consenso di riservatezza. Per le elaborazioni successive, i dati saranno resi anonimi, ovvero non sarà più possibile ricondurre i dati alla Sua persona. La riservatezza è strettamente tutelata durante e dopo la fine del progetto così come in caso di interruzione della Sua partecipazione. Il suo nome non sarà reso noto in nessuna pubblicazione relativa allo studio. Ha il diritto di vedere i dati che la riguardano in qualsiasi momento e correggerli se necessario. Ciò non sarà più possibile dopo che saranno resi anonimi. Tutte le informazioni che la riguardano e che verranno raccolte durante lo studio saranno conservati con riservatezza nei limiti consentiti dalla legge e sarà identificabile soltanto tramite codice in modo da preservare il suo anonimato. I risultati della ricerca saranno presentati nei meetings o nelle pubblicazioni, in ogni caso la Sua identità rimarrà nascosta.

8. DICHIARAZIONE LIBERATORIA

Nelle sperimentazioni sul campo i dispositivi utilizzati (robot, tablet) sono strumenti comunemente reperibili dotati di certificazioni necessarie per l'utilizzo a scopo commerciale. Quindi, funzioneranno adeguatamente. In caso di malfunzionamento o danno a causa di un uso incorretto il consorzio non si assume nessuna responsabilità.

9. POSSIBILITÀ DI COMMERCIALIZZAZIONE

La sua partecipazione a questo progetto di ricerca potrà indurre allo sviluppo di prodotti commercializzabili. Comunque, non riceverà nessun beneficio economico dalla vendita di tali prodotti.

10. CONTATTI

Se dovesse avere qualsiasi domanda riguardo allo studio può comunicare direttamente con I ricercatori/coordinatori dello studio ai seguenti recapiti:

Fondazione Santa Lucia IRCCS
Via Ardeatina 306
00142 Roma (RM)

Dott. Gianfranco Spalletta 06-51501175
Dott.ssa Nerisa Banaj 06-51501193
Dott.ssa Desirée Estela Porcari 06-51501183

Consenso informato

1. Le informazioni che ho ricevuto riguardo allo studio sono soddisfacenti, ho avuto l'opportunità di fare domande e di comprendere le finalità dello studio.

2. Do il mio consenso a partecipare al progetto di ricerca intitolato, ReMember-Me.

3. Confermo di aver compreso che la mia partecipazione è volontaria e che posso ritirare il mio consenso in qualsiasi momento senza fornire spiegazioni e senza nessuna conseguenza legale.

4. Sono d'accordo che i miei dati clinici siano raccolti all'interno di una bancadati centrale. In modo da agevolare le scoperte scientifiche, i miei dati non identificabili saranno resi disponibili al pubblico (in forma assolutamente anonima) per l'uso consentito dalla ricerca in salute e benessere.

5. La natura di questo studio, le procedure, i rischi e i benefici della mia partecipazione e le informazioni di riservatezza, che saranno adottate durante lo studio, mi sono state ampiamente spiegate.

6. Sono d'accordo che in caso di interruzione della mia partecipazione, tutti i miei dati dotati di pseudonimo saranno distrutti su richiesta e che i dati già resi anonimi non potranno essere cancellati.

7. Sono a conoscenza che non ricaverò alcun beneficio economico che possa derivare dai risultati della ricerca.

8. Ho firmato due copie del foglio informativo e del consenso informato. Riceverò una copia di entrambi e i ricercatori conserveranno la seconda copia.

Ho letto personalmente questa copia di dichiarazione di consenso.

Do il consenso alla raccolta di dati personali in accordo alle finalità dello studio.

Do il consenso alla mia partecipazione volontaria allo studio.

Data .....

.....

Firma del partecipante

.....

Cognome e Nome del partecipante

Data .....

.....

Firma del ricercatore

.....

Cognome e Nome del ricercatore

CONSENSO AL TRATTAMENTO DEI DATI PERSONALI

Informativa Privacy ai sensi degli artt. 13 e 14 del Regolamento (UE) 2016/679 per la partecipazione ad attività di ricerca scientifica

Gentile Signora, Egregio Signore,

in conformità alle disposizioni del Regolamento (UE) 2016/679 (di seguito "**GDPR**"), della normativa italiana di armonizzazione, nonché dei provvedimenti adottati dall'Autorità Garante per la protezione dei dati personali (complessivamente, la "Normativa Privacy") la Fondazione Santa Lucia, con sede in Via Ardeatina, n. 306, 00179, Roma, La informa di quanto segue:

1. TITOLARE DEL TRATTAMENTO

Il Titolare del trattamento è la Fondazione Santa Lucia, con sede in Via Ardeatina, n. 306, 00179, Roma, email: privacy@pec.fondazionesantalucia.it (di seguito "**Titolare**" o la "**Fondazione**").

Il Titolare ha nominato un Responsabile per la Protezione dei Dati (di seguito "DPO"), ai sensi dell'art. 37 del GDPR, raggiungibile all'indirizzo dpo@hsantalucia.it .

2. FONTE E TIPOLOGIA DEI DATI TRATTATI

I Suoi dati personali sono raccolti direttamente presso di Lei ovvero presso soggetti terzi che esercitano la patria potestà o svolgono le funzioni di assistenza o di tutela legale o di amministrazione di sostegno.

Il trattamento[1] effettuato dal Titolare avrà ad oggetto le seguenti tipologie di dati personali (di seguito, i "**Dati**"):

- Dati anagrafici (e.g. nome, cognome, data e luogo di nascita)
- Dati di contatto (es. e-mail, numero di telefono)
- Dati identificativi (es. codice fiscale)
- Dati appartenenti a categorie particolari di dati personali[2], di cui all'articolo 9 del GDPR (es. dati relativi alla salute[3]).

[1] Ai sensi dell'art. 4 §1 n. 2 del GDPR per trattamento si intende "qualsiasi operazione o insieme di operazioni, compiute con o senza l'ausilio di processi automatizzati e applicate ai dati personali o insiemi di dati personali, come la raccolta, la registrazione, l'organizzazione, la strutturazione, la conservazione, l'adattamento o la modifica, l'estrazione, la consultazione, l'uso, la comunicazione mediante trasmissione, diffusione o qualsiasi altra forma di messa a disposizione, il raffronto o l'interconnessione, la limitazione, la cancellazione o la distruzione2.

[2] Ai sensi dell'art. 9 del GDPR per "categorie particolari di dati" si intendono "dati personali che rivelino l'origine razziale o etnica, le opinioni politiche, le convinzioni religiose o filosofiche, o l'appartenenza sindacale, nonché trattare dati genetici, dati biometrici

Il Titolare Le ricorda la necessità di comunicarci prontamente qualsiasi cambiamento dei suddetti dati al fine di consentirci di provvedere al loro aggiornamento o alla loro modifica.

3. FINALITA' DEL TRATTAMENTO

I Dati vengono trattati nel rispetto della Normativa Privacy solo **previo Suo specifico consenso** per la seguente finalità:

a. Espletamento della ricerca dal titolo "ReMember-Me", con riferimento agli obiettivi, alle procedure, ai benefici e rischi della partecipazione, nonché all'impegno operativo e temporale richiesto, come in precedenza meglio descritto nel foglio informativo.
b. Obblighi di legge.

4. MODALITÀ DI TRATTAMENTO E PERIODO DI CONSERVAZIONE

I dati personali verranno trattati con il supporto di mezzi cartacei, informatici o telematici atti a memorizzare, gestire e trasmettere i dati stessi nel rispetto della Normativa Privacy ed in particolare di quanto fissato dall'art. 32 del GDPR mediante l'adozione di misure tecniche ed organizzative adeguate al rischio del trattamento anche rispetto ai profili della sicurezza e riservatezza.

Nell'ambito delle attività di trattamento dei Suoi Dati, gli stessi potranno essere portati a conoscenza di persone autorizzate al trattamento dalla Fondazione, alle quali saranno fornite specifiche istruzioni al riguardo e sulle quali graverà un obbligo di riservatezza.

Il Titolare, nel corso dello studio, utilizzerà tecniche di cifratura o pseudonimizzazione volte a rendere i dati non direttamente riconducibili agli interessati, permettendo di identificare questi ultimi solo in caso di necessità.

I Dati saranno conservati per il periodo strettamente necessario al perseguimento delle finalità elencate al paragrafo 3 nonché per l'ulteriore periodo eventualmente necessario per adempiere a specifici obblighi di legge.

5. BASE GIURIDICA DEL TRATTAMENTO, NATURA OBBLIGATORIA O

intesi a identificare in modo univoco una persona fisica, dati relativi alla salute o alla vita sessuale o all'orientamento sessuale della persona".

[3] Ai sensi dell'art.4 § 1 n. 15 del GDPR per "Dati relativi alla Salute" si intendono "i dati personali attinenti alla salute fisica o mentale di una persona fisica, compresa la prestazione di servizi di assistenza sanitaria, che rivelano informazioni relative al suo stato di salute".

FACOLTATIVA DEL CONFERIMENTO E CONSEGUENZE DI UN EVENTUALE RIFIUTO

Il trattamento dei Suoi dati, anche particolari, si fonda sul Suo specifico consenso ai sensi degli articoli 6.1.a) e 9.2.a) del GDPR. Il conferimento dei Dati è facoltativo. L'eventuale rifiuto di fornire i Dati funzionali all'esecuzione della ricerca su menzionata, non comporta alcuna conseguenza relativamente ad eventuali trattamenti terapeutici in corso, salva l'eventuale impossibilità di dare seguito alle operazioni di ricerca o alle attività connesse al programma di studio. I Suoi dati personali saranno trattati per obblighi di legge, ai sensi dell'art. 6.1. c).

Lei è libero/a di non partecipare alla ricerca o di ritirarsi dalla stessa anche senza preavviso o motivazione. Qualora, durante la ricerca, divengano disponibili dati che possano influenzare la Sua volontà di continuare Lei sarà tempestivamente ed opportunamente informato e, se necessario, Le sarà richiesto nuovamente il consenso a proseguire il trattamento in corso.

6. COMUNICAZIONE E DIFFUSIONE DEI DATI

Fermo restando che i dati personali trattati mediante strumenti anche elettronici, saranno diffusi solo in forma rigorosamente anonimizzata e aggregata, gli stessi potranno venire a conoscenza e/o essere comunicati:

- alle persone autorizzate al trattamento dalla Fondazione, alle quali saranno fornite specifiche istruzioni al riguardo e sulle quali graverà un obbligo di riservatezza;
- alle società esterne/centri di ricerca che agiscono per conto del Titolare stesso, al Comitato Etico e le autorità sanitarie italiane e straniere che potranno conoscere i dati che La riguardano, con modalità tali da garantire la riservatezza della Sua identità.

Eventuali ulteriori soggetti ai quali i dati potranno essere comunicati e che svolgeranno attività di trattamento per conto del Titolare[4] saranno all'uopo nominati Responsabili del trattamento ai sensi dell'art. 28 del GDPR. L'elenco aggiornato dei Responsabili del trattamento è disponibile presso la sede della Fondazione Santa Lucia.

[4] Qualora il Titolare dovesse affidare le operazioni di trattamento a terzi, questi ultimi saranno all'uopo nominati responsabili del trattamento ai sensi dell'articolo 28 del GDPR, previa verifica della conformità dell'attività degli stessi alle disposizioni in materia di protezione dei Dati. Il Titolare ricorrerà unicamente a responsabili del trattamento che presentino garanzie sufficienti per mettere in atto misure tecniche e organizzative adeguate, in modo tale che il trattamento soddisfi i requisiti del GDPR e garantisca la tutela dei diritti dell'interessato.

7. TRASFERIMENTO DI DATI ALL'ESTERO

I dati relativi al presente studio saranno raccolti dal Titolare e trasmessi in forma anonimizzata a centri di ricerca e società esterne, tra le quali Materia Group di Cipro che ha commissionato lo studio che Le è stato descritto, anche in Paesi non appartenenti allo Spazio Economico Europeo che non garantiscono un adeguato livello di protezione dei dati. L'elenco completo è disponibile presso la sede della Fondazione Santa Lucia.

8. DIRITTI DELL'INTERESSATO

Lei ha il diritto di accedere in qualunque momento ai dati che La riguardano, ai sensi degli artt. 15-22 GDPR. In particolare, potrà chiedere la rettifica, la cancellazione ove possibile, la limitazione del trattamento dei dati stessi nei casi previsti dall'art. 18 del GDPR, la revoca del consenso prestato ai sensi dell'art. 7 del GDPR, di ottenere la portabilità dei dati che La riguardano nei casi previsti dall'art. 20 del GDPR, nonché proporre reclamo all'autorità di controllo competente ex articolo 77 del GDPR (Garante per la Protezione dei Dati Personali). Lei può formulare una richiesta di opposizione al trattamento dei Suoi dati ex articolo 21 del GDPR nella quale dare evidenza delle ragioni che giustifichino l'opposizione: il Titolare si riserva di valutare la Sua istanza, che non verrebbe accettata in caso di esistenza di motivi legittimi cogenti per procedere al trattamento che prevalgano sui Suoi interessi, diritti e libertà.

Le richieste vanno rivolte per iscritto al Titolare ovvero al DPO ai recapiti di seguito indicati:

c. Titolare: posta ordinaria all'indirizzo della Fondazione Santa Lucia, Via Ardeatina, 306, 00179, Roma o via pec all'indirizzo privacy@pec.fondazionesantalucia.it ;
d. Data Protection Officer (DPO) all'indirizzo dpo@hsantalucia.it .

Modulo di consenso al trattamento dei dati personali

Io sottoscritto/a _____, nato/a a _____, il _____, in qualità di **soggetto sperimentale**,

- preso atto del foglio informativo del protocollo concernente lo studio dal nome **"ReMember-Me"** che si svolgerà presso la Fondazione Santa Lucia;
- ricevuta e letta l'informativa sul trattamento dei dati personali (anche "informativa privacy");
- avuto a disposizione tempo sufficiente per poter leggere attentamente e comprendere quanto contenuto nel suddetto foglio illustrativo e nell'informativa privacy;
- informato del diritto di ritirarmi dalla ricerca in qualsiasi momento, senza dover dare spiegazioni e senza compromettere l'assistenza medica futura;

Presto il consenso al trattamento dei dati personali, anche appartenenti a categorie particolari (dati relativi alla salute) di cui all'articolo 9 del GDPR, per le finalità specificate nell'informativa privacy (c.d. "consenso al trattamento dei dati")

□ si, presto il consenso

□ no, nego il consenso

Accetto di apparire nelle foto scattate allo scopo di diffondere le informazioni riguardanti lo studio in oggetto sui social media (Facebook, Twitter, sito web del progetto, etc.)

□ si, presto il consenso

□ si, presto il consenso ma il mio volto dovrà essere offuscato

□ no, nego il consenso

Luogo e data _____ Firma _____

Annex 4: Informed consent in Greek (MATERIA)

ΕΝΤΥΠΑ ΣΥΓΚΑΤΑΘΕΣΗΣ
για συμμετοχή σε ερευνητικό πρόγραμμα
(Τα έντυπα αποτελούνται συνολικά από …….. σελίδες)

Τίτλος του Προγράμματος στο οποίο καλείστε να συμμετάσχετε

ReMember-me: *Έξυπνος βοηθός για την πρόληψη και τον εντοπισμό της γνωστικής έκπτωσης, την προώθηση της γνωστικής λειτουργικότητας και την ενεργή συμμετοχή των ατόμων της τρίτης ηλικίας στο κοινωνικό πλαίσιο.*

Στο έντυπο αυτό δίνονται εξηγήσεις σε απλή και κατανοητή γλώσσα σχετικά με το τι ζητείται από εσάς ή/και τι θα συμβεί σε εσάς, εάν συμφωνήσετε να συμμετάσχετε στο πρόγραμμα:

1. Περιγράφονται οποιοιδήποτε κίνδυνοι μπορεί να υπάρξουν ή ταλαιπωρία που τυχόν θα υποστείτε από την συμμετοχή σας στο πρόγραμμα.
2. Επεξηγείται με κάθε λεπτομέρεια ποιος ή ποιοι θα έχουν πρόσβαση στα δεδομένα που σας αφορούν και θα προκύψουν από το πρόγραμμα που θα συμμετάσχετε ή/και άλλο υλικό/δεδομένα που εθελοντικά θα δώσετε για το πρόγραμμα.
3. Δίνεται η χρονική περίοδος για την οποία οι υπεύθυνοι του προγράμματος θα έχουν πρόσβαση στις πληροφορίες ή/και υλικό σας αφορά.
4. Επεξηγείται το τί ευελπιστούν να μάθουν οι υπεύθυνοι του προγράμματος σαν αποτέλεσμα και της δικής σας συμμετοχής.
5. Δίνεται μία εκτίμηση για το όφελος που μπορεί να υπάρξει για τους ερευνητές ή/και χρηματοδότες αυτού του προγράμματος.
6. **Δεν πρέπει να συμμετάσχετε, εάν δεν επιθυμείτε ή εάν έχετε οποιουσδήποτε ενδοιασμούς που αφορούν τη συμμετοχή σας στο πρόγραμμα.**
7. Εάν αποφασίσετε να συμμετάσχετε, πρέπει να αναφέρετε εάν είχατε συμμετάσχει σε οποιοδήποτε άλλο πρόγραμμα έρευνας μέσα στους τελευταίους 12 μήνες.
8. Εάν αποφασίσετε να μην συμμετάσχετε και είστε ασθενής, η θεραπεία σας δεν θα επηρεαστεί από την απόφασή σας.
9. **Είστε ελεύθεροι να αποσύρετε οποιαδήποτε στιγμή εσείς επιθυμείτε τη συγκατάθεση για την συμμετοχή σας στο πρόγραμμα.**
10. Εάν είστε ασθενής, η απόφασή σας να αποσύρετε την συγκατάθεση σας, δεν θα έχει οποιεσδήποτε επιπτώσεις στη θεραπεία σας.
11. Πρέπει όλες οι σελίδες των εντύπων συγκατάθεσης να φέρουν το ονοματεπώνυμο και την υπογραφή σας.

Επιστημονικός υπεύθυνος του Προγράμματος στο οποίο καλείστε να συμμετάσχετε
Μαρίνα Πολυκάρπου

Επίθετο:	.....	Όνομα:	.....
Υπογραφή:		Ημερομηνία:	

(Εντυπο ΕΕΒΚ03)

1/9

ΕΝΤΥΠΑ ΣΥΓΚΑΤΑΘΕΣΗΣ **για συμμετοχή σε ερευνητικό πρόγραμμα** (Τα έντυπα αποτελούνται συνολικά από …….. σελίδες)
Τίτλος του Προγράμματος στο οποίο καλείστε να συμμετάσχετε
ReMember-me: *Έξυπνος βοηθός για την πρόληψη και τον εντοπισμό της γνωστικής έκπτωσης, την προώθηση της γνωστικής λειτουργικότητας και την ενεργή συμμετοχή των ατόμων της τρίτης ηλικίας στο κοινωνικό πλαίσιο.*

Χρονική διάρκεια του Προγράμματος:
36 μήνες

Δίδετε συγκατάθεση για τον εαυτό σας ή για κάποιο άλλο άτομο;	
Εάν πιο πάνω απαντήσατε για κάποιον άλλο, τότε δώσετε λεπτομέρειες και το όνομα του.	

Ερώτηση	ΝΑΙ ή ΟΧΙ
Συμπληρώσατε τα έντυπα συγκατάθεσης εσείς προσωπικά;	
Τους τελευταίους 12 μήνες έχετε συμμετάσχει σε οποιοδήποτε άλλο ερευνητικό πρόγραμμα;	
Διαβάσατε και καταλάβατε τις πληροφορίες για ασθενείς ή/και εθελοντές;	
Είχατε την ευκαιρία να ρωτήσετε ερωτήσεις και να συζητήσετε το Πρόγραμμα;	
Δόθηκαν ικανοποιητικές απαντήσεις και εξηγήσεις στα τυχόν ερωτήματά σας;	
Καταλαβαίνετε ότι μπορείτε να αποσυρθείτε από το πρόγραμμα, όποτε θέλετε;	
Καταλαβαίνετε ότι, εάν αποσυρθείτε, δεν είναι αναγκαίο να δώσετε οποιεσδήποτε εξηγήσεις για την απόφαση που πήρατε;	
(Για ασθενείς) καταλαβαίνετε ότι, εάν αποσυρθείτε, δεν θα υπάρξουν επιπτώσεις στην τυχόν θεραπεία που παίρνετε ή που μπορεί να πάρετε μελλοντικά;	
Συμφωνείτε να συμμετάσχετε στο πρόγραμμα;	
Με ποιόν υπεύθυνο μιλήσατε;	

Επίθετο:	.....	Όνομα:	.....
Υπογραφή:		Ημερομηνία:	

(Εντυπο ΕΕΒΚ03)

ΕΝΤΥΠΑ ΣΥΓΚΑΤΑΘΕΣΗΣ **για συμμετοχή σε ερευνητικό πρόγραμμα** (Τα έντυπα αποτελούνται συνολικά από …….. σελίδες)
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……

Σύντομη περιγραφή του προγράμματος (διαδικασίες και σκοπός).
Σας προσκαλούμε να πάρετε μέρος σε αυτή την Ευρωπαϊκή μελέτη που αφορά άνδρες και γυναίκες άνω των 65 ετών. Μελετάμε τον έγκαιρο εντοπισμό και την πρόληψη των καταστάσεων που προκαλούν δυσκολίες στη μνήμη και στη καθημερινή λήψη αποφάσεων. Μελετάμε, δηλαδή, αυτό που λέγεται νευρογνωστική διαταραχή σε άτομα τρίτης ηλικίας. Επίσης, εξετάζουμε τρόπους ενδυνάμωσης του εγκεφάλου.

Λεπτομέρειες του τι θα ζητηθεί ή/και τι θα συμβεί στους συμμετέχοντες στο πρόγραμμα
Η συμμετοχή σας στο πρόγραμμα θα αφορά τη δοκιμή δύο συσκευών (ρομπότ με οθόνη και έξυπνο ρολόι χειρός) και κάποιων εφαρμογών (λ.χ., εφαρμογή που μετρά τη νοητική κατάσταση, σοβαρά παιχνίδια, κ.ά.). Η χρονική διάρκεια που η κοινοπραξία έχει σχεδιάσει να αφιερωθεί στη διαδικασία των δοκιμών είναι 6 μήνες συνολικά. Η δική σας συμμετοχή θα αφορά ένα μικρότερο χρονικό διάστημα κατά τη διάρκεια της περιόδου αυτής, συνολικά περίπου 8 εβδομάδων. Συγκεκριμένα, κατά τη συμμετοχή σας στη μελέτη μία ομάδα ερευνητών (ψυχολόγος και νοσηλευτής) θα σας προμηθεύσουν με ένα ρομπότ με οθόνη και ένα έξυπνο ρολόι και θα σας εξηγήσουν πώς να τα χρησιμοποιείτε. Η χρήση τους δεν θα απαιτεί πολύπλοκη ενασχόληση από τη μεριά σας ενώ η ερευνητική ομάδα αναλαμβάνει πλήρως την ευθύνη για οποιαδήποτε δυσλειτουργία των συσκευών ή επιδιόρθωση χρειαστούν χωρίς καμία απαίτηση από εσάς ή συνέπεια για εσάς. Οι ερευνητές θα σας εκπαιδεύσουν στο σύστημα του ReMember-Me και θα είναι στη διάθεσή σας για λύσουν όλες τις απορίες ή σε περίπτωση που αντιμετωπίσετε κάποια δυσκολία. Επίσης, οι ερευνητές θα μετρήσουν τη νοητική σας κατάσταση με απλά τεστ ή θα σας ζητήσουν να απαντήσετε σε κάποιες ερωτήσεις. Στην οθόνη του ρομπότ θα προσφέρονται μία σειρά από τεστ, βίντεο ασκήσεις και παιχνίδια που ενδυναμώνουν τη μνήμη και γενικότερα το νου (π.χ., γνωστικά παιχνίδια). Τα τεστ έχουν σκοπό την εκτίμηση της νοητικής λειτουργίας και των ικανοτήτων σας, καθώς επίσης την καταγραφή της προσωπικής σας αξιολόγησης ως προς την ποιότητα ζωής και την ευεξία σας. Τα δεδομένα που θα συλλεχθούν από το έξυπνο ρολόι αφορούν λειτουργίες του σώματός σας για παράδειγμα το πόσο περπατάτε μέσα σε μια μέρα και την ποιότητα του ύπνου σας. Αντίστοιχα, μέσω των παιχνιδιών θα συλλέγονται δεδομένα σχετικά με την νοητική σας λειτουργία όπως για παράδειγμα το αν θυμάστε μία συγκεκριμένη ημερομηνία κάποιας εορτής ή αν μπορείτε να πείτε τους μήνες του χρόνου αντίστροφα. Με τον καιρό, με βάση αυτά τα δεδομένα θα μπορείτε να ελέγχετε αν τα πάτε καλύτερα. Επίσης, το σύστημα ReMember-Me σας δίνει τη δυνατότητα να μοιραστείτε τα δεδομένα αυτά, εφόσον το

ΕΝΤΥΠΑ ΣΥΓΚΑΤΑΘΕΣΗΣ
για συμμετοχή σε ερευνητικό πρόγραμμα
(Τα έντυπα αποτελούνται συνολικά από …….. σελίδες)

Τίτλος του Προγράμματος στο οποίο καλείστε να συμμετάσχετε

ReMember-me: *Έξυπνος βοηθός για την πρόληψη και τον εντοπισμό της γνωστικής έκπτωσης, την προώθηση της γνωστικής λειτουργικότητας και την ενεργή συμμετοχή των ατόμων της τρίτης ηλικίας στο κοινωνικό πλαίσιο.*

επιθυμείτε με κάποιο μέλος της οικογένειάς σας (ηλικίας 18 και άνω) ή κάποιον επαγγελματία υγείας που σας παρακολουθεί. Οποιαδήποτε στιγμή μπορείτε να ανακαλέσετε αυτή τη δυνατότητα και να διακοπεί η πρόσβαση των ατόμων αυτών στα δεδομένα σας.

Εφόσον συμφωνήσετε να συμμετάσχετε, θα σας ζητηθεί να υπογράψετε το παρόν έγγραφο συγκατάθεσης που περιέχει τα στοιχεία των ερευνητών του προγράμματος και του οποίου θα κρατήσετε αντίτυπο. Οποτεδήποτε αλλάξετε γνώμη για αυτό και θελήσετε να διακόψετε την συμμετοχή σας, μπορείτε να το κάνετε άμεσα, χωρίς να χρειασθεί να δώσετε καμία εξήγηση και φυσικά χωρίς καμία απολύτως συνέπεια για εσάς (λ.χ., στις μελλοντικές σας ιατρικές υπηρεσίες). Επιπλέον, εάν το θελήσετε, μπορείτε να ζητήσετε να διαγραφούν όλα τα δεδομένα που έχουν καταχωρηθεί (ανώνυμα) για εσάς, χωρίς να δώσετε καμία εξήγηση και χωρίς να έχετε καμία απολύτως συνέπεια.

Λεπτομέρειες της χρηματοδότησης του ερευνητικού προγράμματος
Το έργο χρηματοδοτείται από το πρόγραμμα Active Assisted Living Programme-Ageing Well in the Digital World.

Λεπτομέρειες οποιονδήποτε κινδύνων που πιθανόν να υπάρξουν ή ταλαιπωρία που τυχόν θα υποστούν οι συμμετέχοντες στο πρόγραμμα.
Κατά τη συμμετοχή σας στη μελέτη δεν προβλέπεται να υπάρξει άμεσος ή έμμεσος κίνδυνος για την υγεία σας. Επιπλέον δεν θα γίνει καμία αλλαγή στις ιατρικές οδηγίες που έχετε λάβει και δεν θα επηρεαστεί, σε καμία περίπτωση, η φαρμακευτική σας αγωγή. Αξίζει να σημειωθεί ότι τα δεδομένα σας θα μεταδίδονται στους συνεργάτες μας ηλεκτρονικά και ανώνυμα. Ωστόσο, οι συνεργάτες μας θα τα επεξεργάζονται εκτός σύνδεσης (off-line) και σε δεύτερο χρόνο. Για το λόγο αυτό, το σύστημα δεν παρέχει τη δυνατότητα άμεσης αντιμετώπισης επειγουσών καταστάσεων που μπορεί να προκύψουν. Οτιδήποτε προκύψει από την κλινική εξέταση για το οποίο χρειάζεται να ενημερωθεί ο θεράπων ιατρός σας, θα σας γνωστοποιηθεί, εάν έχετε αναφέρει ότι επιθυμείτε να ενημερώνεστε για τα αποτελέσματα των κλινικών εξετάσεων, σε οποιαδήποτε φάση του έργου (δείτε πεδίο: «Σε περίπτωση που ανακαλυφθούν νέες πληροφορίες που επηρεάζουν άμεσα την υγεία σας θα θέλατε να πληροφορηθείτε;» πιο κάτω). Όπως επίσης, οτιδήποτε παθολογικό γίνει αντιληπτό κατά την μετέπειτα επεξεργασία των δεδομένων σας.

(Εντυπο EEBK03)

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Λεπτομέρειες για το ποιες πληροφορίες ή/και τι υλικό θα συλλεγεί στα πλαίσια του προγράμματος, ποιος/ποιοι θα έχουν πρόσβαση σε αυτά και για πόσο χρονικό διάστημα.
Καθ΄ όλη τη διάρκεια της συμμετοχής σας στο πρόγραμμα θα συλλέγονται μόνο οι απολύτως απαραίτητες πληροφορίες για τη μελέτη. Οι πληροφορίες αυτές θα είναι ανώνυμες και δεν θα μοιράζονται με κανέναν άλλον εκτός από την ερευνητική ομάδα του προγράμματος στην Κύπρο. Επίσης, οι εφαρμογές που θα χρησιμοποιηθούν για τη συλλογή των πληροφοριών δουλεύουν μέσω αλγόριθμων, κάτι που σημαίνει ότι δεν καταγράφουν σε καμία περίπτωση προσωπικά δεδομένα, βίντεο ή φωτογραφίες σας παρά μόνο στοιχεία θέσης (αριθμούς). Παραδείγματος χάριν, η οθόνη πάνω στο ρομπότ δε καταγράφει εικόνα, παρά μόνο τις απαντήσεις που δίνετε σε αυτό, ενώ το έξυπνο ρολόι μετρά την ταχύτητα βάδισης και τα βήματά σας μέσω της κίνησης εμπρός-πίσω που κάνει το χέρι σας όταν κινείστε, αλλά δεν καταγράφει οποιοδήποτε προσωπικό στοιχείο. Κατά τη διάρκεια της συμμετοχής σας, θα έχετε την ευκαιρία να κρατήσετε σπίτι σας τις συσκευές του προγράμματος αλλά μόνο για όσο διαρκεί η συμμετοχή σας σε αυτό. Επίσης, θα έχετε την ευκαιρία να πείτε την γνώμη σας σχετικά με τις προτιμήσεις σας. Οποιαδήποτε εισήγηση για αλλαγή ή τροποποίηση της πλατφόρμας θα είναι πολύτιμη για εμάς. Τέλος, διευκρινίζεται ότι τα ανώνυμα δεδομένα που θα συλλεχθούν από εσάς θα διατηρηθούν έως και 5 έτη μετά τη λήξη του προγράμματος σε φυλασσόμενο και ασφαλή χώρο στον οποίο έχει πρόσβαση μόνο η ομάδα έργου. Μετά το τέλος της μελέτης και για την καταστροφή τους θα ακολουθηθούν συγκεκριμένες διαδικασίες καταστροφής εγγράφων ώστε να διασφαλιστεί η ανωνυμία των συμμετεχόντων και η προστασία των δεδομένων τους. Επιπλέον, η πρόσβαση στα δεδομένα θα διακόπτεται για όποιους ερευνητές αποσυρθούν από τη μελέτη.

Επίθετο:	……	Όνομα:	……
Υπογραφή:		Ημερομηνία:	

(Εντυπο ΕΕΒΚ03)

ΕΝΤΥΠΑ ΣΥΓΚΑΤΑΘΕΣΗΣ
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ΟΠΟΥ ΙΣΧΥΕΙ, ΜΕΛΛΟΝΤΙΚΗ ΑΠΟΘΗΚΕΥΣΗ ΚΑΙ ΧΡΗΣΗ ΒΙΟΛΟΓΙΚΩΝ ΔΕΙΓΜΑΤΩΝ ΚΑΙ ΠΡΟΣΩΠΙΚΩΝ ΔΕΔΟΜΕΝΩΝ: Παρακαλούμε σημειώστε και υπογράψτε είτε αριστερά είτε δεξιά	
Εκτός από τους σκοπούς του παρόντος προγράμματος που θα διαρκέσει ..... χρόνια **Αποδέχομαι** ☐ όπως: Υπογραφή:	Εκτός από τους σκοπούς της παρούσας μελέτης που θα διαρκέσει ..... χρόνια **Δεν αποδέχομαι** ☐ όπως: Υπογραφή:
τα βιολογικά μου δείγματα (παρειακά επιχρίσματα ή σάλιο ή DNA) και γενετικά δεδομένα μου που θα φυλάσσονται στο ..... **<u>να μπορούν να κρατηθούν πέραν των ..... χρόνων και να χρησιμοποιηθούν σε μελλοντικές μελέτες</u>** αφού πρώτα εγκριθεί κάτι τέτοιο από την Εθνική Επιτροπή Βιοηθικής Κύπρου (ΕΕΒΚ) μετά από σχετικό αίτημα ανανέωσης προς την ΕΕΒΚ από τον υπεύθυνο ερευνητή του παρόντος προγράμματος. Καταλαβαίνω ότι θέματα εμπιστευτικότητας θα ισχύουν πάντοτε.	

Σε περίπτωση που ανακαλυφθούν νέες πληροφορίες που επηρεάζουν άμεσα την υγεία σας θα θέλατε να πληροφορηθείτε;		
ΝΑΙ ☐	ΟΧΙ ☐	ΔΕΝ ΜΠΟΡΩ ΝΑ ΑΠΟΦΑΣΙΣΩ ΤΩΡΑ, ΝΑ ΕΡΩΤΗΘΩ ΕΚ ΝΕΟΥ ΕΦΟΣΟΝ ΥΠΑΡΞΕΙ ΑΝΑΓΚΗ ☐

Λεπτομέρειες για το ποια δεδομένα θα προκύψουν για σας στα πλαίσια του προγράμματος και ποιος/ποιοι θα έχουν πρόσβαση σε αυτά και για πόσο χρονικό διάστημα.
Ισχύει το πρωτόκολλο διαχείρισης δεδομένων όπως ακριβώς περιγράφεται στην παράγραφο «Λεπτομέρειες για το ποιες πληροφορίες ή/και τι υλικό θα συλλεγεί στα πλαίσια του προγράμματος, ποιος/ποιοι θα έχουν πρόσβαση σε αυτά και για πόσο χρονικό διάστημα.»

Επίθετο:	.....	Όνομα:	.....
Υπογραφή:		Ημερομηνία:	

(Εντυπο ΕΕΒΚ03)

6/9

ΕΝΤΥΠΑ ΣΥΓΚΑΤΑΘΕΣΗΣ
για συμμετοχή σε ερευνητικό πρόγραμμα
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ReMember-me: *Έξυπνος βοηθός για την πρόληψη και τον εντοπισμό της γνωστικής έκπτωσης, την προώθηση της γνωστικής λειτουργικότητας και την ενεργή συμμετοχή των ατόμων της τρίτης ηλικίας στο κοινωνικό πλαίσιο.*

Αναμενόμενο όφελος για τους συμμετέχοντες
Η συμμετοχή σας στο πρόγραμμα ReMember-Me θα είναι εθελοντική. Δεν θα έχετε οικονομικό όφελος ή υλικό όφελος από τη συμμετοχή σας στη μελέτη, και δεν θα σας επιβαρύνει με κανένα χρηματικό κόστος. Η συμμετοχή σας θα σας βοηθήσει όμως να αποκτήσετε νέες γνώσεις, λ.χ. τεχνολογικές, και θα σας βοηθήσει να είστε πιο ενεργός/ή και κινητοποιημένος/η. Επίσης, θα συνεισφέρετε σημαντικά στη βελτίωση της ποιότητας ζωής άλλων ανθρώπων και στην εξέλιξη της γνώσης και της επιστήμης.

Αναμενόμενο όφελος για ερευνητές ή/και χρηματοδότες
Η κοινοπραξία του ReMember-Me θα έχει όφελος μόνο μετά την ολοκλήρωση του προγράμματος και σε περίπτωση που η εμπορευματοποίηση του προϊόντος είναι επιτυχής όπως προγραμματίζεται. Επιπλέον, αναμένονται οφέλη σε επιστημονική δραστηριότητα, εμπειρία και γνώση που θα προκύψουν σωρευτικά από την εμπλοκή των εταίρων στις ερευνητικές δραστηριότητες.

Λεπτομέρειες συνθηκών τερματισμού ή πρόωρης διακοπής του ερευνητικού προγράμματος.
Δεν προβλέπεται να προκύψει αιφνίδια διακοπή του προγράμματος πριν την προκαθορισμένη ημερομηνία ολοκλήρωσής του. Ωστόσο, θα ενημερώνεστε λεπτομερώς για οποιεσδήποτε αλλαγές στο πρόγραμμα (λ.χ., αναφορικά με τη διάρκεια, έναρξη και ολοκλήρωση συμμετοχής σας, κ.ά.) μόνο εφόσον αυτές σας επηρεάζουν. Το ίδιο ισχύει και στη σπάνια περίπτωση πρόωρου τερματισμού του προγράμματος. Σε αυτή την περίπτωση, θα ενημερωθείτε όσο νωρίτερα δυνατόν για τις επερχόμενες αλλαγές και θα πρέπει να επιστραφούν οι συσκευές που κρατούσατε στο πλαίσιο της μελέτης. Ωστόσο, εάν μέχρι τότε έχετε εξοικειωθεί με το σύστημα ReMember-Me και νιώθετε ότι θα σας λείψει στην καθημερινότητά σας, οι ερευνητές θα σας παράσχουν δωρεάν ένα πακέτο γνωστικών ασκήσεων καθώς και λύσεις κοινωνικοποίησης στην κοινότητα ώστε να συνεχίζετε να διατηρείτε τον εγκέφαλό σας σε εγρήγορση. Επιπλέον, θα σας δοθούν επιλογές παρόμοιων προϊόντων που μπορείτε να αγοράσετε μόνοι σας από ανεξάρτητους προμηθευτές αν εσείς το επιθυμείτε.

Χώρος και χρονική διάρκεια φύλαξης δεδομένων ή/και βιολογικών δειγμάτων που θα ληφθούν στο πλαίσιο του προγράμματος
Οι οποιεσδήποτε πληροφορίες έντυπης μορφής που συλλέγονται φυλάσσονται στο γραφείο της Υπεύθυνης του Έργου και στο οποίο πρόσβαση έχει μόνο η ομάδα έργου της Κύπρου. Ο χώρος διαθέτει ειδικά ερμάρια που κλειδώνουν για τη φύλαξη των δεδομένων του έργου στα οποία δεν έχει πρόσβαση οποιοδήποτε τρίτο άτομο.

(Εντυπο EEBK03)

7/9

ΕΝΤΥΠΑ ΣΥΓΚΑΤΑΘΕΣΗΣ **για συμμετοχή σε ερευνητικό πρόγραμμα** (Τα έντυπα αποτελούνται συνολικά από …….. σελίδες)
Τίτλος του Προγράμματος στο οποίο καλείστε να συμμετάσχετε
ReMember-me: *Έξυπνος βοηθός για την πρόληψη και τον εντοπισμό της γνωστικής έκπτωσης, την προώθηση της γνωστικής λειτουργικότητας και την ενεργή συμμετοχή των ατόμων της τρίτης ηλικίας στο κοινωνικό πλαίσιο.*

Επίθετο:	……	Όνομα:	……
Υπογραφή:		Ημερομηνία:	

Περιγραφή διαδικασιών χειρισμού δεδομένων ή/και βιολογικών δειγμάτων συμμετεχόντων που θα αποσυρθούν από τη μελέτη πριν την ολοκλήρωση της.
Έχετε το δικαίωμα να αποσυρθείτε οποιαδήποτε στιγμή το επιθυμείτε από τη μελέτη χωρίς να χρειαστεί να αιτιολογήσετε την επιλογή σας αυτή. Επίσης, οποιαδήποτε στιγμή, έχετε το δικαίωμα να ζητήσετε τη μη χρήση ή την πλήρη διαγραφή των ανώνυμων δεδομένων που συλλέχθηκαν από εσάς κατά τη διάρκεια της μελέτης. Εάν επιλέξετε να αποσυρθείτε από τη μελέτη αλλά δεν επιθυμείτε διαγραφή των δεδομένων σας, τότε, για σκοπούς έρευνας τα ανώνυμα δεδομένα σας θα χρησιμοποιηθούν για το σύνολο των αναλύσεων χωρίς να απαιτείται οποιαδήποτε άλλη ενέργεια από εσάς.

Πλήρη στοιχεία επικοινωνίας και θέση ατόμου στο οποίο οι συμμετέχοντες μπορούν να υποβάλλουν παράπονα ή καταγγελίες που αφορούν το πρόγραμμα στο οποίο συμμετέχουν.
Υπεύθυνος Παραπόνων - Δρ. Μάριος Γεωργίου Γραμματέας Κυπριακού Συμβουλίου Αναζωογόνησης (ΚΥ.Σ.ΑΝ.) Διευθυντής Νοσηλευτικών Υπηρεσιών του American Medical Center/American Heart Institute Fellow of the European Resuscitation Council (FERC) (Ευρωπαϊκό Συμβούλιο Αναζωογόνησης) Ονούφριου Κληρίδη 1Α, Λατσιά 2224, Λευκωσία Διεύθυνση ηλεκτρονικού ταχυδρομείου: healthcaretraining@primehome.com Τηλέφωνο επικοινωνίας: 70 009903

Πλήρη στοιχεία επικοινωνίας και θέση ατόμου στο οποίο οι συμμετέχοντες μπορούν να απευθυνθούν για περισσότερες πληροφορίες ή διευκρινήσεις για το ερευνητικό πρόγραμμα.
Υπεύθυνη Έργου - Μαρίνα Πολυκάρπου Αθαλάσσης 41, 2221 Λατσιά, Λευκωσία Τηλέφωνα: 22573577, 99607567 Φαξ: 22571555 Ηλ. Ταχυδρομείο: agecare@cytanet.com.cy

(Εντυπο EEBK03)

ΕΝΤΥΠΑ ΣΥΓΚΑΤΑΘΕΣΗΣ **για συμμετοχή σε ερευνητικό πρόγραμμα** (Τα έντυπα αποτελούνται συνολικά από …….. σελίδες)
Τίτλος του Προγράμματος στο οποίο καλείστε να συμμετάσχετε
ReMember-me: *Έξυπνος βοηθός για την πρόληψη και τον εντοπισμό της γνωστικής έκπτωσης, την προώθηση της γνωστικής λειτουργικότητας και την ενεργή συμμετοχή των ατόμων της τρίτης ηλικίας στο κοινωνικό πλαίσιο.*

Επίθετο:	……	Όνομα:	……
Υπογραφή:		Ημερομηνία:	

(Εντυπο ΕΕΒΚ03)

9/9

Annex 5: Privacy Policy

Privacy Policy

This information sheet (hereafter called Privacy Policy) describes the personal information we collect from you, why we collect it and how it is used and stored, and otherwise processed in the context of the ReMember – Me Project.

1. Introduction

Your privacy is important to us. We know the 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 (https://eur-lex.europa.eu/eli/reg/2016/679/oj). We respect the principles of data processing: lawfulness, fairness, transparency, 'purpose limitation', 'data minimisation', 'accuracy', 'storage limitation', 'integrity and confidentiality', 'accountability' and the rules in force in this field.

This Privacy Policy ("Policy") describes how the personally identifiable information ("Personal Information") you may provide on the context of the ReMember – Me Project ("Project ") and any of the project activities ("Activities" or "Services") is collected, protected, used and stored, and otherwise processed.

This Privacy Policy also describes your data protection rights.

You have the right to:

· information about the processing of your personal data;

· obtain access to the personal data held about you;

· ask for incorrect, inaccurate or incomplete personal data to be corrected;

· request that personal data be erased when it's no longer needed or if processing it is unlawful;

· object to the processing of your personal data for marketing purposes or on grounds relating to your particular situation;

· request the restriction of the processing of your personal data in specific cases;

· receive your personal data in a machine-readable format and send it to another controller ('data portability');

· request that decisions based on automated processing concerning you or significantly affecting you and based on your personal data are made by natural persons, not only by computers. You also have the right in this case to express your point of view and to contest the decision.

Also, this Privacy Policy describes the choices available to you regarding our use of your Personal Information and how you can access and update this information.

In short: This Privacy Policy is a legally binding agreement between you ("User", "you" or "your") and the ReMember-Me consortium ("Operator", "we", "us" or "our").

By accessing and using the ReMember – Me system and any of the project activities, you acknowledge that you have read, understood, and agree to be bound by the terms of this Policy.

If you would like to contact us to understand more about this Policy or wish to contact us concerning any matter relating to individual rights and your Personal Information, you should contact the research contact person at the address given below (CONTACT PERSONS).

2. Information about the ReMember – Me Project

Full name of the project: Smart assistant to prevent and detect cognitive decline, promote cognitive function and social inclusion among older adults

Acronym: ReMember – Me (hereafter the ”ReMember – Me Project”)

Project No: AAL-2019-6-188-CP

Funding: This work was supported by a grant of the Romanian National Authority for Scientific Research and Innovation, CCCDI – UEFISCDI and of the AAL Programme with co-funding from the European Union’s Horizon 2020 research and innovation programme project number AAL-2019-6-188-CP within PNCDI III.

The ReMember – Me Project is a multinational project that aims to detect and prevent cognitive decline early on in older adults. The ReMember – Me Project is partially funded by AAL joint programme and “Research and Innovation Foundation” (CY), UEFISCDI (RO), IMoH (IT), “Bizkaia Foru Aldundia/ Diputación Foral de Bizkaia” (ES), National Research, Development and Innovation Office (HU) and “Vlaio” (BE) under the Grant Agreement number AAl- 2019-6- 188- CP. More information about our project is available on this link: https://www.rememberme-aal.eu/.

The ReMember-Me consortium is responsible for the project implementation. The consortium consists of eight partner organisations (hereafter Partners) located in six countries.

Project Coordinator: AgeCare (Cyprus) Ltd – Materia Group - Cyprus

Technical University of Cluj – Napoca - Romania

Ana Aslan International Foundation – Romania

IRCCS Fondazione Santa Lucia – Italy

ESKILARA S. Koop. Txikia – Spain

ARTOFINFO Kereskedelmi es Szolgaltato Korlatolt Felelossegu Tarsasag – Hungary

ePoint BVBA – Belgium

Sint Jan Berchmanstehuis part of the Integro group – Belgium

This Privacy Policy applies to your use of our Services or any of the ReMember – Me Project Activities.

In view of the new regulations on the protection of personal data, introduced by EU Regulation 2016/679, "GDPR", which is the basis of the legislation on the processing of personal data and the protection of this data for all EU member countries, we wish to inform you that we guarantee our firm commitment to process your personal data in a transparent, secure and respectful manner, in accordance with all the rights you have under the law. For this purpose, please read below the main elements that we consider useful for you to know on this subject, in your capacity as a "data subject". For any information about your rights in this field or if you have any question, you can contact the research contact person at the address given below (CONTACT PERSONS).

When you join the ReMember – Me Project, personal data provided by you will be processed by the Lead Administrators of the platform - AgeCare (Cyprus) Ltd. – Materia Group, Ana Aslan International Foundation, IRCCS Fondazione Santa Lucia, Sint Jan Berchmanstehuis part of the Integro Group (hereafter called Lead Administrators) as Joint Data Controllers and by the System developers - Technical University of Cluj – Napoca, ARTOFINFO Kereskedelmi es Szolgaltato Korlatolt Felelossegu Tarsasag , ePoint BVBA as Joint Data Processors.

We take protecting your personal data very seriously and will always take all reasonable steps within our power to make sure your information is safe. By accepting our terms and conditions and using our Services, you confirm that you are at least 18 years of age and are giving your consent for the Data Controllers and Data Processors to store and process your personal data.

If you do not wish to give your consent, you will not be able to access the ReMember – Me system and its Services. You can withdraw your consent at any time without any negative legal consequences for you.

Your participation in the ReMember – Me project is voluntary and you can choose to stop participating at any time. You can withdraw your consent at any time without giving any reason. It shall be as easy to withdraw as to give consent. The withdrawal of consent shall not affect the lawfulness of processing based on consent before its withdrawal. There will be no negative consequences for you if you decide to withdraw your consent.

If you should decide to withdraw your consent, please contact the research contact person and let her/him know of your intention. You can contact the research contact person at the address given below (CONTACT PERSONS).

3. Types of personal data we collect

The Partners collect personal information that you voluntarily provide after giving your consent to participate in the ReMember – Me project, when registering at the ReMember – Me system and while using it at home.

The following data categories are processed:

§ In the Registration process, the following of your personal data will be processed: first name, last name, gender, age, weight, height, years of education, living status, country and city of residence, email address, phone number, username, password, level of assistance needed, personal interests and experience.

§ In the Baseline Assessment performed on the ReMember – Me system, the following of your personal data will be processed: Remember – Me Cognitive Assessment Scale (RMCAS), 4-item Personal Wellbeing scale, 15-item Geriatric Depression Scale (GDS), Rapid Assessment of Physical Activity (RAPA), 11-item De Jong Gierveld Loneliness Scale, motor function and activities, single item Sleep Quality scale.

§ In the ReMember – Me Testing and Evaluation Phase, the following of your personal data will be processed: information and results from detection exercises, results from games, rehabilitation activities, your user's activities, your frequency of system's usage, hours of usage of the system and its devices, number of registrations per category, physiological parameters measured by ReMember – Me devices like physical activity data from the fitness tracker, data from sleep analyser, any information you decide to share with us through discussions, interviews, questionnaires, correspondence, follow-up visits, as well as data providing performance, satisfaction, motivation feedback from participant's point of view .

§ Credentials - We collect your IP address, passwords, password hints, and similar security information used for authentication and account access.

4. Sources of data

Personal information will be collected from you, from discussions with researchers of the ReMember – Me Project, your baseline assessment, usage and interaction with the ReMember – Me system, measurements of the wearable devices provided to you, from interviews, questionnaires and scales such as the ReMember-Me Cognitive Assessment Scale (ReMCAS)), 4-item Personal Wellbeing scale, 15-item Geriatric Depression Scale (GDS), Rapid Assessment of Physical Activity (RAPA), 11-item De Jong Gierveld Loneliness Scale, motor function and activities, single item Sleep Quality scale and from processed data providing performance, satisfaction, motivation.

5. Legal basis for processing

Legal basis for processing your personal data is your consent.

You acknowledge that you have read this Privacy Policy and agree to all its terms and conditions. By accessing and using the ReMember – Me system and Services you agree to be bound by this Policy. If you do not agree to abide by the terms of this Policy, you are not authorized to access or use the ReMember – Me system and Services.

If you should decide to withdraw your consent, please contact the research contact person and let her/him know of your intention. You can contact the research contact person at the address given below (CONTACT PERSONS).

The withdrawal of your consent will not affect the lawfulness of the collection and processing of your data based on your consent up until the moment where you withdraw your consent.

6. How to exercise these rights

Any requests to exercise your rights can be directed to the research contact person at the address given below (CONTACT PERSONS). Please note that we may ask you to verify your identity before responding to such requests. Your request must provide sufficient information that allows us to verify that you are the person you are claiming to be or that you are the authorized representative of such person. You must include sufficient details to allow us to properly understand the request and respond to it. We cannot respond to your request or provide you with Personal Information unless we first verify your identity or authority to make such a request and confirm that the Personal Information relates to you.

7. Data processors

We rely on the following organisations to process your personal data:

Organisation (data processor)	Processed data categories	Server location
Technical University of Cluj – Napoca (Romania)	Physical activity data	Romania
Technical University of Cluj – Napoca (Romania)	Sleep activity	Romania
ARTOFINFO Kereskedelmi es Szolgaltato Korlatolt Felelossegu Tarsasag (Hungary)	Registration process	Hungary
ARTOFINFO Kereskedelmi es Szolgaltato Korlatolt Felelossegu Tarsasag (Hungary)	Baseline assessment	Hungary
ARTOFINFO Kereskedelmi es Szolgaltato Korlatolt Felelossegu Tarsasag (Hungary)	Games	Hungary

We collect personal information that you voluntarily provide to us when registering at the ReMember – Me system, expressing an interest in obtaining information about us, when doing baseline assessment and detection exercises, playing games as well as participating in activities on the Meet People platform. The personal information that we collect depends on the context of your interactions with us and your usage of the ReMember – Me system during its testing.

All personal information that you provide to us must be true, complete and accurate, and you must notify us of any changes to such personal information.

8. Why do we collect this data?

Personal data collected during registration, baseline assessment, detection exercises is needed for registration purposes as well as defining your cognitive status through the tests and scales described in point 2. Types of personal data we collect. Moreover, the Partners want to validate the ReMember – Me system and monitor its effectiveness, adapt its services to the needs of older adults and improve them.

It is important for you to know that ReMember – Me results do not and cannot replace medical examination by a physician.

Results from this study will be used for the ReMember – Me Project and for scientific purposes only. Personal data will be processed in a manner that ensures appropriate security and confidentiality of personal data, which includes preventing unauthorized access to or use of personal data and the equipment used for processing. Recorded information will be processed during the phase of data analysis and will be included in project internal reports or later in scientific publications. Your recorded information will only be processed for the purposes of the project ('purpose limitation') and limited to what is necessary in relation to the purposes for which they are processed ('data minimisation'). The results of this study may be published in scientific magazines, conference proceedings or books.

9. What are your rights?

Once you have provided your personal data, several rights are recognized under the Data Protection Legislation, which you can in principle exercise free of charge, subject to statutory exceptions. In particular, you have the following rights:

· Right to request access to your Personal Information that we store and have the ability to access your Personal Information.

• Right to withdraw your consent: you may withdraw your consent at any time you choose and at your own initiative by contacting us at (CONTACT PERSONS) The withdrawal of your consent will not affect the lawfulness of the collection and processing of your data based on your consent up until the moment where you withdraw your consent.

• Right to rectify your data: you have the right to access, review, and rectify your personal data. You may be entitled to ask us for a copy of your information, to review or correct it if you wish to review or rectify any information. You also have the right to request us to complete the Personal Information you believe is incomplete.

• Right to erasure: you have the right to the erasure of all the personal data processed by as described herein in case it is no longer needed for the purposes for which the personal data was initially collected or processed, in accordance with the Data Protection Legislation.

• Right to object or restriction of processing: under certain circumstances described in the Data Protection Legislation, you may ask for a restriction of processing or object to the processing of your personal data.

• Right to data portability: under certain circumstances described in the Data Protection Legislation, you have the right to receive the Personal Data processed in a format which is structured, commonly used and machine-readable and to transmit this data to another service provider.

These rights may be limited, for example, if fulfilling your request would reveal personal data about another person, or if you ask us to delete information which we are required by law to keep or have compelling legitimate interests in keeping. To exercise any of these rights, you can get in touch with us using the details set out below. If you have unresolved concerns, you have the right to lodge a complaint with an EU data protection authority where you live, work, or where you believe a breach may have occurred.

10. How long is your personal data stored?

We retain your personal data for the duration of the ReMember – Me Project (i.e. until 1st of April 2024) or for a shorter period as long as your data are required to fulfil the activities set out in the Information letter and this Privacy Policy. After such period your personal data may be archived, where possible in an anonymised format, in accordance with applicable legal or contractual requirements (the requirements of the contract's number AAL-2019-6-188-CP for ReMember – Me Project: 3 years after the end of the project).

We may also retain your personal data if it is reasonably necessary to comply with any legal obligations, meet any regulatory requirements, resolve any disputes or litigation, or as otherwise needed to enforce this Privacy Policy and prevent fraud and abuse. To determine the appropriate retention period for the information we collect from you, we consider the amount, nature, and sensitivity of the personal data, the potential risk of harm from unauthorised use or disclosure of the data, the purposes for which we process the personal data, and whether we can achieve those purposes through other means, and the applicable legal requirements.

11. How is your personal data shared with third parties?

We only share or disclose information as described in the Information letter and this Privacy Policy, including with third parties. Your personal data will also be shared with government authorities and/or law enforcement officials if required for the purposes

above, if mandated by law or if required for the legal protection of the data controller(s) legitimate interests in compliance with applicable laws and the contract's number AAL-2019-6-188-CP for ReMember – Me Project.

12. Is your personal data transferred outside the European Economic Area (EEA)?

We do not intend to transfer the data that we collect from you to a destination outside the EEA. Should this however become the case (e.g. as a result of Brexit), we will put in place appropriate safeguards to ensure that such transfers comply with Data Protection Legislation, either by putting in place Standard Contractual Clauses approved by the European Commission as ensuring an adequate protection or by ensuring that the transfer is done to an organisation that complies with Privacy Shield in case the transfer is made to the United States of America.

13. What security measures are put in place?

Appropriate technical and organisational measures are implemented in order to ensure an appropriate level of security of your personal data. In the event personal information is compromised as a result of a security breach and where the breach is likely to result in a high risk to your rights and freedoms, we will make the necessary notifications, as required under the Data Protection Legislation.

Information security

We secure information you provide on computer servers in a controlled, secure environment, protected from unauthorized access, use, or disclosure. We maintain reasonable administrative, technical, and physical safeguards in an effort to protect against unauthorized access, use, modification, and disclosure of Personal Information in its control and custody. However, no data transmission over the Internet or wireless network can be guaranteed. Therefore, while we strive to protect your Personal Information, you acknowledge that

(i) there are security and privacy limitations of the Internet which are beyond our control;

(ii) the security, integrity, and privacy of any and all information and data exchanged between you and the Website and Services cannot be guaranteed; and

(iii) any such information and data may be viewed or tampered with in transit by a third party, despite best efforts.

Data breach

In the event we become aware that the security of the ReMember – Me system and Services has been compromised or users Personal Information has been disclosed to unrelated third parties as a result of external activity, including, but not limited to,

security attacks or fraud, we reserve the right to take reasonably appropriate measures, including, but not limited to, investigation and reporting, as well as notification to and cooperation with law enforcement authorities. In the event of a data breach, we will make reasonable efforts to notify affected individuals if we believe that there is a reasonable risk of harm to the user as a result of the breach or if notice is otherwise required by law. When we do, we will send you an email or get in touch with you over the phone or mail you a letter.

14. Where do we store your data?

We keep your information for as long as necessary to fulfil the purposes outlined in this Privacy Policy unless otherwise required by law and the contract's number AAL-2019-6-188-CP for ReMember – Me Project. During the research and development phases of the project's 3 years lifetime phases each technical partner will provide its own infrastructure for hosting the developed components and storing. Personal data collected through the ReMember- Me system will be stored in Romania, Hungary and Belgium into TUC, AOI and EP premises. After the end of the project when exploitation, IP and business plans will be established it will be decided how hosting and data storage will be managed under a live production environment.

15. Data retention, account deactivation and deletion

We retain your personal data as long as you maintain your account in the ReMember – Me system in order to provide you with the platform's services. If you delete your account, your personal data will generally stop being visible to other users within 24 hours. Your past data will be anonymized and stored for a period of 12 months after the account deactivation.

If your account becomes dormant, it will be deactivated after approximately 6 months.

If you withdraw your consent from this Privacy Policy, you will no longer have access to our services and your account will be deactivated.

16. Legal jurisdiction

The use of the ReMember – Me system is governed by the laws of the 4 countries in which it is tested i.e. Cyprus, Romania, Italy and Belgium. In accessing the platform, you consent to the exclusive jurisdiction of the Cypriot, Romanian, Italian and Belgian courts in all disputes arising out of or relating to the use of the website.

17. Changes and amendments to this policy

In short: Yes, we will update this Privacy Policy as necessary to stay compliant with relevant laws.

We may update this Privacy Policy or the terms related to the ReMember – Me system and Services from time to time. The updated version will be indicated by an

updated “Revised” date and the updated version will be effective as soon as it is accessible. If we make material changes to this privacy policy, we may notify you either by prominently posting a notice of such changes or by directly sending you a notification. We encourage you to review this Privacy Policy frequently to be informed of how we are protecting your information.

Changes to this policy will be announced to you through a pop-up message on the ReMember – Me system and on the Privacy Policy page. The new updated Privacy Policy will be sent to your email address.

The Lead Administrators may change this policy by updating this page. Please check this page regularly to ensure that you are happy with any changes we make to our Privacy Policy. Any updated version of this Privacy Policy will be effective immediately upon the posting of the revised Policy unless otherwise specified. Your continued use of the ReMember – Me system and Services after the effective date of the revised Policy (or such other act specified at that time) will constitute your consent to those changes. However, we will not, without your consent, use your Personal Information in a manner materially different from what was stated at the time your Personal Information was collected.

This policy is effective as of April 30th 2021.

18. Privacy of children

We do not knowingly collect any Personal Information from children under the age of 18. If you are under the age of 18, please do not submit any Personal Information through the Website and Services. We encourage parents and legal guardians to monitor their children's Internet usage and to help enforce this Policy by instructing their children never to provide Personal Information through the Website and Services without their permission. If you have reason to believe that a child under the age of 18 has provided Personal Information to us through the Website and Services, please contact us. You must also be at least 18 years of age to consent to the processing of your Personal Information.

19. CONTACT PERSONS

For further information about your rights as a participant in the testing phases, or if you are not satisfied with the way this study is being carried out, or if you have any question or complaint during the testing phase, please contact the leading researcher:

- [Name, surname of researcher/s]
- [End-user organization name]
- [Full address of end-user organization]
- [Telephone number of researcher/ s]

- [Email address of researcher/s]

This document was last updated on …… (March 11, 2021)

Questions, comments, remarks, requests or complaints regarding this Privacy Policy are welcome and should be addressed to [mail contact].

Annex 6: Personal data table

Type of personal data collected	Source of data	Description of tests/ scales/ surveys	Purposes for collection
Name and surname	During registration and explicit consent form		Registration purpose + Facilitation of human-robot interaction + communication with authorized contacts
Email address	During registration		Registration + Communication with the user
Country and City of residence	During registration		Registration
Phone number	During registration		Registration + Communication with the user

Gender	During registration and socio-demographic survey conducted by researchers before the field trials		Gender representation in the study. Sex, age, education, and geographical area have several significant multivariate interactions with most of the assessment varibles that ReMember - Me is going to collect (loneliness, cognitive status, physical activity and personal well-being)
Username	During registration		Registration
Password	During registration		Registration
Weight	During registration		Calculation of Body Mass Index (hereafter BMI). There is a significant relationship between the BMI of normal cognitive individuals and risk of dementia. BMI (along with levels of physical activity) is also important for identifying frail seniors
Height	During registration		

Age	During registration		Age representation in the study. Sex, age, education, and geographical area have several significant multivariate interactions with most of the assessment varibles that ReMember - Me is going to collect (loneliness, cognitive status, physical activity and personal well-being)
Years of education	During registration and socio-demographic survey conducted by researchers before the pilot trials		Needed for the administration of the ReMCAS + getting information about the profile of system's users (needed for the business plan and project's evaluation)
Living status	During registration and socio-demographic survey conducted by researchers before the pilot trials		Needed to facilitate communication with authorized contacts and design of training plan + background characteristics (such as marital status, sex and living arrangements) were identified as important loneliness-provoking factors
Have assistance	During registration		Profile of primary end users taking part in the field trials

Interests	During registration		This information could be used to match with students and also assist in the personalisation of the system
Experience	During registration		
Technology literacy	Collected by researchers before the pilot trials through a survey		Getting information about the profile of system's users (needed for the business plan and project's evaluation)
The Remember – Me Cognitive Assessment Scale (RMCAS)	ReMember - Me system	RMCAS is a rapid screening instrument for mild cognitive dysfunction. It assesses different cognitive domains: attention and concentration, executive functions, memory, language, visuoconstructional skills, conceptual thinking, calculations, and orientation	Categorisation of primary end users as cognitively fit or with cognitive decline as to adapt stimulation/intervention to general cognitive status + Monitoring cognition as to detect signs of incipient cognitive decline

15-items Geriatric Depression Scale	ReMember - Me system	The Geriatric Depression Scale is a screening test used to identify symptoms of depression in older adults	Cognitive deficits occur in depression, especially in the elderly, affecting various domains such as attention, executive functions, memory and processing speed. On the other hand, depression and apathy symptoms (which the GDS can measure) are associated with a two-fold increased risk of developing dementia in individuals without manifest cognitive impairment. Thus, the presence of depressive or apathetic symptoms is both an explanatory and a risk factor for cognitive decline which is our variable of interest. Additionally, in case the subject consistently reports severe depressive symptoms, the system may suggest to primary end users to contact their physician

11-item De Jong Gierveld Loneliness Scale		The de Jong Gierveld Loneliness Scale can be a questionnaire that is 11-item to evaluate both general loneliness and two certain kinds of loneliness. This scale includes two subscales: a three-item loneliness that is emotional (aimed at loneliness as a result of not enough an in depth, intimate relationship) and a three-item social loneliness subscale (aimed at loneliness because of the not enough a wider social networking).	There is an inverse association between dementia risk and number of close relationships. While loneliness and social isolation are known to be related to depression that is itself linked to incident cognitive decline, the association of depressive symptoms and apathy in individuals reporting perceived social isolation can determine a circular-causal relationship and increase the odds of progressing to cognitive deterioration. Moreover, impoverished social relationships lead to a diminution in cognitive stimulation, thus eroding the cognitive reserve, and raising the odds for cognitive deterioration in cognitively unimpaired older subjects. As the proposed system will try to enhance social engagement (and to supposedly reduce social isolation) in healthy elderlies at risk for developing cognitive deterioration, the scale is crucial for measuring the quality or quantity of social relationships.

Single-item Sleep Quality Scale	ReMember - Me system	It is a simple and practical sleep quality assessment.The Sleep Quality Scale possesses favorable measurement characteristics relative to lengthier or more frequently administered sleep questionnaires in patients with insomnia and depression	Trouble falling or staying asleep, poor sleep quality, and short or long sleep duration are gaining attention as potential risk factors for cognitive decline and dementia, including Alzheimer's disease. Additionally, poor sleep quality might contribute to cognitive and functional decline, while healthy sleep appears to play an important role in maintaining brain health with age, and may play a key role in dementia prevention
Motor function and activities	ReMember - Me system		Encouraging evidence indicates that being more physically active is associated with a lower risk of Alzheimer's disease and a slower rate of cognitive decline in older adults. Indeed, there is a positive association between motor abilities and cognitive test performance, as well as a separate independent association between physical activity and cognitive performance. In both cases, better motor abilities or higher levels of physical activity are associated with better cognitive performance. Thus, motor abilities and levels of physical activity need to be separately measured and monitored. The latters are also crucial for identifying frailty in the elderlies.

Personal well-being Scale (4 items)		It is easy to use with good psychometric properties, suitable for routine use in quality improvement of life.	Wellbeing in old age across domains of function can take various forms, and it typically highlights three main areas of function important for high overall wellbeing – high cognitive function, high physical function and physical health, and good psychosocial wellbeing. As we embrace a model where these multiple markers of wellbeing are measured we will be able to verify how well being-associated variables are correlated and to what other variables they are related. Plus, by monitoring potential changes, the system can proactively act to alert caregivers and heathcarers about consistent decrements in self-reported well-being.
Rapid Assessment of Physical Activity questionnaire	ReMember - Me system	It is a tool for quickly assessing the level of physical activity of older adults. (https://depts.washington.edu/hprc/resources/products-tools/rapa/)	
Hearing acuity	Screening volunteers prior to participation in field trials		Usually, subjects with very severe (and non-compensated) loss of hearing/visual acuity are excluded from clinical trials
Visual acuity			

Information from detection exercises	ReMember - Me system		Detection exercises and performance on games counts in identification of vulnerable domains and is calculated in the total report and adjustment of training plans every month, 3-months, 6-months, 12-months (user/caregivers/healthcare professional can choose from settings)
Games results	ReMember - Me system		
Stimulating games results	ReMember - Me system		For the production of personalised gaming plan (in order to keep exercises interesting and engaging)
Data from fitness tracker Fitbit Inspire 2:			
1. Effort: Number of steps, distance, calories burned etc.	Fitbit Inspire 2		These parameters can be used for assessing the physical condition of an older adult

2. Activities: type and intensity	Fitbit Inspire 2		Types of activities (e.g. Running, Walking, etc.) can be used for assessing the physical condition of older adults and their preferences for a certain physical activity. Classifying the level of intensity at which the older adult performs an activity (Sedentary, Lightly Active, Fairly Active, Very Active) can offer insight over a person's condition
3. Sleep duration	Fitbit Inspire 2		This data is used to analyse the older adults' sleep quality over longer periods of time and to determine sleeping patterns for creating insights for professionals and caregivers to evaluate their condition
4. Sleep cycles: deep, light, REM phases	Fitbit Inspire 2		
5. Sleep Score	Fitbit Inspire 2		
Data from Withings Sleep Analyzer:			
1. Sleep duration	Withings Sleep Analyzer		
2. Sleep cycles: deep, light, REM phases	Withings Sleep Analyzer		

3. Sleep Score	Withings Sleep Analyzer		
Frequency of system's usage	ReMember - Me system		Statistical purposes + analysis of ReMember- Me system' s usage
Different users' activities	ReMember - Me system		
Number of registrations per category	ReMember - Me system		
Time spent in the system	ReMember - Me system		