SOCIAL INTERACTIVE CARE SYSTEM TO SUPPORT THE WELLBEING OF PEOPLE LIVING WITH DEMENTIA

D1.2 ETHICAL METHODOLOGIES

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The project *Many-Me* is funded under the AAL Programme 2016 Call 'Living well with dementia'

Short description

This deliverable describes the "ethical and legal issues" that may appear during the development of the project. Many-Me will handle personal data and therefore it is important to consider all ethical, legal and private issues that may appear in the several countries where the project is implemented

A template was distributed to all partners to indicate their ethical and legal policies as well as the specific issues that are of relevance to them. This information is the basis of this report called Ethical Methodologies. Based on the inventory made an informed consent form was produced and already used during the interviews with end-users during the user requirement analysis.

This deliverable will oversee all relevant issues and serve as an input to train those responsible for the user involvement on how to comply with the recommendations mentioned in the report.

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Content

1. Introduction

Many-Me intends to develop an interactive ICT driven platform for persons who suffer from mild cognitive complaints; sometimes referred to as early stage dementia; also, the caregivers (formal and informal) are amongst the intended end-users. The project foresees three pilot rounds in which this interactive ICT based system is tested with the end-users. These end-users are either the elderly patients themselves, or their formal and informal caregivers. During three rounds of pilots the system will be tested with these end-users' groups.

1.1 Objectives

The general objective of the project is to develop a social interactive care system based on ICT, in order to offer early stage dementia patients and their caregivers, support to cope with the disease and live an active and meaningful life. Our solution will be co-created together with early stage dementia patients and their caregivers, optimised and customised to their specific needs.

The main goal is the development of easy to use, intuitive interfaces, offered to primary end-users, means and support to stay active and independent, keep their habits, adopt helpful routines, connect with peers and make friends. The system will also provide safety for outdoor activities, permanent monitoring capabilities and it acts as an emergency system when necessary.

Caregivers (formal and informal) will have access to networking, education and training, so they can learn effective ways to provide care and reduce their burden. The system recommends care giving activities based on profiles and context. It also allows close monitoring of patient care plans with input from informal caregivers, automatic notifications and guidance to help patients stay healthy and perform activities of daily living.

The ambition is to build and bring to market this unified system, making it available for every EU citizen to improve their health and wellbeing. From the six different countries (Switzerland, Austria, The Netherlands, Cyprus, Romania and Poland) that form the project consortium, four (The Netherlands, Austria, Switzerland and Cyprus) will test the solution and will help develop a ready to market product that can be applicable in every EU country.

The objective of this deliverable is to give an inventory of ethical and legal issues that might occur during the project and could affect the participation of the end-users and would also define the ways in which these end-users should be invited to participate and protect their privacy.

1.2 Scope of the deliverable

Four end-user organisations are involved in Switzerland, the Netherlands, Cyprus, and Austria. These end-user organisations will approach the three target groups mentioned earlier on to perform a user needs requirement through interviews and surveys. After the development of the system these end-users organisations will invite the target groups to use and give feedback on the system.

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Based on the Ethics Issues table currently in use for research under HORIZON 2020, the European Research Collaboration Program, we can conclude that has to work with humans, collects personal data and involves so called third countries (i.e. non-EU member states, such as Switzerland).

Apart from the end-user organisations who will collect personal data and need informed consent for this, the system developers should identify as soon as possible what kind of personal data are needed. Furthermore, in the quality assurance system, it should be made clear how these data are stored and protected and who monitors this and this concerns not only the data on national level where every *Many-Me* partner is based, but also on EU level when these data care collected by the coordinator based in the Netherlands.

Therefore, this deliverable provides an overview of EU and national requirements and it is the responsibility of each partner to study these in detail and decide on what measures should be taken. Moreover, the coordinator Drimpy (NL) should pay attention to the protection of data during the whole course of the project and describe transparent procedures on how these data will be stored based on the quality procedures of *Many-Me.*

2. Current regulations in force

2.1 European Union

Relevant EU regulation:
EU Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data (OJ L 281, 23.11.1995, p. 31)

News on the revision of Directive 95/46/EC

Regulation (EU) No 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) (OJ L 119, 4.5.2016, p. 1)

2.2 Personal data

Many-Me concerns research which involves collecting or processing personal data, regardless of the method used *(e.g. interviews, questionnaires, direct online retrieval etc.)*. 'Personal data' means any information, private or professional, which relates to an identified or identifiable natural person (for the full definition, *see Article 2(a) of EU Directive 95/46/EC*).

Examples: *name, address, identification number, e-mail, CV, bank account number, phone number, medical records*.

There are various potential identifiers, including full name, pseudonyms, occupation, address or any combination of these. Individuals are not considered 'identifiable' if identifying them requires excessive effort. Completely anonymised data does not fall under the data privacy rules (as from the moment it has been completely anonymised). 'Processing of personal data' means any operation (or set of operations) performed on personal data, either manually or by automatic means. This includes:

– collection (digital audio recording, digital video caption, etc.)
– recording
– organisation & storage (cloud, LAN or WAN servers)
– adaptation or alteration (merging sets, appification, etc.)
– retrieval & consultation
– use
– disclosure by transmission, dissemination or otherwise making available (share, exchange, transfer)
– alignment or combination
– blocking, deleting or destruction.

Examples: *creating a mailing list or a list of participants, managing a database, accounting records on personnel costs, time-sheets, project planning with names.*

Processing normally covers any action that uses data for research purposes (even if interviewees, human volunteers, patients, etc. are *not* actively included in the research). Data may come from any type of research activity (ICT research, genetic sample collection, tissue storage, personal records (financial, criminal, education, etc.), lifestyle and health information, family histories, physical characteristics, gender and ethnic background, location tracking and domicile information, etc.).

2.3 Anonymisation, Codification and Identifiable Information.

When dealing with privacy and data protection issues, it is important to correctly distinguish between the following categories of data: When personal data is collected, processed and stored, this data can remain **identifiable**, it can be **codified** or completely **anonymised**.

Anonymised data is data that cannot be linked back to the individual. Codified data is data where the most obvious identifiers such as names and addresses are replaced with an indirect system of identification, usually through codes. It remains possible to link the indirect identifiers with names and addresses. For each category of data, different rules might apply.

2.4 Data transfer

Data transfer within EU/EEA countries — Data transfers within the EU/EEA are not subject to specific requirements (i.e. specific authorisations or other restrictions). One only needs to comply with the general requirements of Directive 95/46/EC.

Data transfer to non-EU countries — Data transfers to non-EU countries are normally subject to the following rules:
– for non-EU countries on the Commission list of countries offering adequate protection*: no additional requirements*

Currently (March 2016) this list covers: Andorra, Argentina, Canada (only private (commercial) sector, not public sector), Switzerland, the Faroe Islands, Guernsey, Israel, the Isle of Man, Jersey, New Zealand, Uruguay.

2.5 Switzerland[1]

Since the project *Many-Me* does not collect data from dementia people to improve and control their health status, there is no need to contact an ethics authority. The collection of data is carried out according to the national laws for data protection.

Authorities:

- Eidgenössischer Datenschutz- und Öffentlichkeitsbeauftragter (responsible for all issues regarding data security)
- Kantonale or eidgenössische Ethikkommission (competence depending on regional scope; must be informed and / or asked to state their opinion in cases in which sensitive medical data of identifiable testing persons shall be handed over to third persons)

Main regulations:

- Bundesverfassung, Art. 13 (Protection of privacy, including the protection of private and family life, home, mail and telecommunication, financial secrecy)
- Bundesgesetz über den Datenschutz (revised January 1, 2014)
- Verordnung zum Bundesgesetz über den Datenschutz (revised December 1, 2010)
- Schweizerisches Zivilgesetzbuch, Art. 28-28l
- Bundesgesetz über die Forschung am Menschen (Humanforschungsgesetz, HFG, revised January 1, 2014)

2.6 The Netherlands[2]

[1] The information in this paragraph is provided by the Swiss partner.
[2] The information in this paragraph is provided by the Dutch partner.

The main rules for handling personal data are laid down in the Personal Data Protection Act (WBP). The Dutch Data Protection Authority is the supervisory body for the Dutch Personal Data Protection Act.

The Dutch DPA supervises processing of personal data in order to ensure compliance with laws that regulate the use of personal data. The most important laws are the Dutch Data Protection Act (Wet bescherming persoonsgegevens), the Police Data Act (Wet politiegegevens) and the Basic Registration of Persons Act (Wet basisregistratie personen).

The Dutch Personal Data Protection Act (Wet Bescherming Persoonsgegevens, WBP) protects the rights of individual citizens in the Netherlands. The task of monitoring compliance with the laws governing the use of personal data in the hands of the Dutch Data Protection Authority (College Bescherming Persoonsgegevens, CBP).

In general, one can say, that given the scope of the *Many-Me* project, these are the most important aspects to take into account:

- Make sure to de-identify the data during collection or directly after collection. This can be done by removing names, addresses, telephone numbers and IP addresses from e.g. datasets, transcripts and fieldnotes;
- Make sure to only process coded data (data that cannot be traced back to the individual person);
- Collect only the variables you really need to answer your research question. Remove variables which you do not need to answer the specific research question in the data set used for analysis. This reduces the chances on identification of the individual person;
- To reduce identification risks: aggregate and substitute variables where possible. For instance change birth data into age, reduce the numbers in postal codes, use BMI instead of body mass and length;
- Store and process data always on the network drives of the organisation. Use data encryption when working outside the network.
- Never use email or open internet connections to transport identifying data including video and sound recordings, such as Wetransfer, FTP

2.7 Cyprus[3]

The Office of the Commissioner for Personal Data Protection is responsible to provide the permission for acquiring and processing personal information from participants. The researcher has to fill in a simple form and this office will provide a consent form to provide it to the research participants in order to give their permission to process their data.

[3] The information in this paragraph is provided by the Cypriotic partner.

The Processing of Personal Data (Protection of Individuals) Law of 2001 was introduced in the context of harmonization with the European Data Protection legislation and amended in 2003 in order to align domestic legislation with Directive 95/46/ EC of the European Parliament and the Council Decision of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data.

'Personal data' or merely 'data' are defined under section 2 of the Law as 'all information which refers to a living data subject'. Anonymous data are not considered to be personal data. A simple email address, even though it may not disclose its owner's identity, as well as the online habits of a person that can create his profile, can constitute personal data. 'Sensitive data' are data concerning racial or ethnic origin, political opinions, religious or philosophical beliefs, participation in a union, club or trade union organization, health, sexual life and sexual orientation, as well as anything relevant to criminal prosecutions or sentencing.

Personal data may be processed only if the data subject has unambiguously given his consent. Personal data may be processed without the data subject's consent where:
(a) processing is necessary for compliance with a legal obligation to which the controller is subject;
(b) processing is necessary for the performance of a contract to which the data subject is party, or in order to take measures at the data subject's request prior to entering into a contract;
(c) processing is necessary in order to protect the vital interests of the data subject,
(d) processing is necessary for the performance of a task carried out in the public interest or in the exercise of public authority vested in the controller or a third party to whom the data are communicated;
(e) processing is necessary for the purposes of the legitimate interests pursued by the controller or by the third party to whom the personal data are communicated, on condition that such interests override the rights, interests and fundamental freedoms of the data subjects.

The collection and processing of sensitive data is prohibited except when one or more of the following conditions are fulfilled:
(a) the data subject has given his explicit consent, unless such consent has been obtained illegally or is contrary to accepted moral values or a specific law provides that consent does not lift the prohibition;
(b) processing is necessary so that the controller may fulfil his obligations or carry out his duties in the field of employment law;
(c) processing is necessary to protect the vital interests of the data subject or of another person where the data subject is physically or legally incapable of giving his consent;
(d) processing is carried out by a foundation, association or other non-profit-making organisation which has political, philosophical, religious or trade-union aims, and relates solely to its members and such other persons with whom they said association, foundation or organisation retains relations by reason of its purposes. Such data may be communicated to third parties only if the data subject gives his consent;
(e) the processing relates solely to data which are made public by the data subject or are necessary for the establishment, exercise or defence of legal claims before the Court,

(f) the processing relates to medical data and is performed by a person providing health services by profession and has a duty of confidentiality or is subject to relevant codes of conduct, on condition that the processing is necessary for the purposes of preventive medicine, medical diagnosis, the provision of care or the management of health-care services;
(g) processing is necessary for the purposes of national needs or national security, as well as criminal and reform policy, and is performed by a service of the Republic or an Organisation or Foundation authorized for this purpose by a service of the Republic and relates to the detection of crimes, criminal convictions, security measures and investigation of mass destructions;
(h) processing is performed solely for statistical, research, scientific and historical purposes, on condition that all the necessary measures are taken for the protection of the data subjects;
(i) processing is performed solely for journalistic purposes or in the framework of artistic expression and as long as the right to privacy and family life is not violated.

Transmission of data which have undergone processing or are intended for processing after their transmission to any country shall be permitted after a license of the Commissioner

At the time of collection of the personal data the controller shall provide the data subject info about his identity and the purpose of the processing.

Every person has the right to know whether the personal data relating to him are or were processed.

The data subject has the right to object, at any time, on compelling legitimate grounds relating to his particular situation, to the processing of data relating to him. The objection shall be in writing and addressed to the controller, and must contain a request for specific action to be taken, such as rectification, temporary abstention from use, blocking, abstention from transmission or erasure. The controller must reply in writing on these objections within fifteen days from the submission of the request.

A Commissioner for the Protection of Personal Data is appointed, with relevant duties such as the issue directions for the uniform application of provisions concerning the protection of individuals with regard to the processing of personal data, to examine complaints relating to the application of this Law and the protection of the rights of the applicants etc.

Notification

The controller must notify the Commissioner in writing about the establishment and operation of a filing system or the commencement of processing. The controller must state his full name, business name or title and his address, the address where the filing system is established or the main equipment necessary for the processing is installed, a description of the purpose of the processing of the data which are or are intended to be processed or which are included or intended to be included in the filing system, a description of the category or categories of data subjects, the categories of data which are or are intended to be processed or which are included or intended to be included in the filing system, the period of time for which he intends to carry out the processing or to keep the filing system,

the recipients or categories of recipients to whom he communicates or may communicate the data, the proposed transmissions of data to third countries and the purpose thereof, the basic characteristics of the system and the measures for the security of the filing system or of the processing.

The controller is discharged from the obligation to notify in some cases, for example where processing is performed solely for purposes directly connected with the work to be done and is necessary for the fulfilment of a legal obligation or for the performance of a contract provided that the data subject has been previously informed or processing is performed by doctors or other persons who provide health services and concerns medical data.

Persons who provide health services such as clinics, hospitals, health centers, recovery and detoxication centers, insurance funds and insurance companies as well as the controllers of personal data when the processing is performed in the framework of programs relating to telemedicine operations or provision of medical services through a network, are not excluded from this provision.

2.8 Austria[4]

Since the end-user organization in Austria is not collecting data from people suffering from Alzheimer disease, there is no need to contact an ethics authority. The collection and storage of data takes place according to national law - Datenschutzgesetz

Authorities: Bundeskanzleramt: Österreichische Datenschutzkommission

Main regulations:
•Bundesgesetz über den Schutz personenbezogener Daten. Datenschutzgesetz 2000. BGBI. Inr. 165 del 17/8/1999 (Federal Law Gazette I No. 165/1999)
•Datenschutzverordnung des. BPräs: This legal ordinance controls basic principles on data investigation and processing, data usage, its transmission and deletion.
•Informationssicherheitsgesetz: This act regulates basic rights of data privacy and the duty to give information
•Wiener Antidiskriminierungsgesetz (LBI 35/2004): This act regulates the abatement of discrimination referring to the access to social, health and education as well as public services. It focuses on the non-discrimination and equal treatment regarding sex, age, disability, ethnic group, religion, ideology and sexual orientation

Datenschutzgesetz 2000:
http://www.ris.bka.gv.at/GeltendeFassung.wxe?Abfrage=bundesnormen&Gesetzesnummer=10001597
Datenschutzverordnung des Bundespräsidenten:
https://www.ris.bka.gv.at/GeltendeFassung.wxe?Abfrage=Bundesnormen&Gesetzesnummer=10000688

[4] The information in this paragraph is provided by the Austrian partner.

Informationssicherheitsgesetz:
https://www.ris.bka.gv.at/GeltendeFassung.wxe?Abfrage=Bundesnormen&Gesetzesnummer=20001174

3. Ethical issues in *Many-Me*

Apart from the obvious example, the medical field, research protocols in social sciences, ethnography, psychology, environmental studies, security research, etc. may involve the voluntary participation of research subjects and the collection of data that might be considered as personal. Ethics also matter for scholarly publication. Major scientific journals in many areas will increasingly require ethics committee approval before publishing research articles.

For the *Many-Me* project a preliminary check has been made with the H2020 Ethics Issues table and what results is the following:

- *Many-Me* deals with human beings
- *Many-Me* uses personal data
- *Many-Me* has one non-EU member from Switzerland in the consortium which requires special attention to data transport, if any; however, Switzerland is on the Commission list of countries offering adequate protection: therefore, no additional requirements are needed; please see paragraph 2.1.3 Data transfer

Furthermore, an Awareness list data protection and privacy issues was sent to the end-users organisation (Please see Annex). The results confirmed the same issues as above.

Consequently, the most evident measures that should be taken within the *Many-Me* project are:

- to arrange informed consent from the research subjects
- to anonymize their personal data
- to ensure a solid data protocol on storage and removal by the coordinator and by the end-user partners in their respective countries according to national regulations

4. Informed consent

Declared one of the most pivotal principles in research ethics in many international conventions and guidelines, informed consent is meant to guarantee the voluntary participation in research and is probably the most important procedure to address privacy issues in research. Informed consent consists of three components: adequate information, voluntariness and competence. This implies that, prior to consenting to participation, participants should be clearly informed of the research goals, possible adverse events, possibilities to refuse participation or withdraw from the research, at any time, and without consequences. Research participants must also be competent to understand the information and should be fully aware of the consequences of their consent. Although informed consent is often seen in the context of clinical research, this principle is important for all types of research, including the social sciences.

Participation must be entirely voluntary and one must obtain and clearly document participants' informed consent in advance.

Participants must be given an **informed consent form** and detailed **information sheets** that:
– are written in a language and in terms they can fully understand
– describe the aims, methods and implications of the research, the nature of the participation and any benefits, risks or discomfort that might ensue
– explicitly state that participation is voluntary and that anyone has the right to refuse to participate and to withdraw their participation, samples or data at any time — without any consequences
– state how biological samples and data will be collected, protected during the project and either destroyed or reused subsequently
– state what procedures will be implemented in the event of unexpected or incidental findings (in particular, whether the participants have the right to know, or not to know, about any such findings).

One must ensure that potential participants have fully understood the information and do not feel pressured or coerced into giving consent. Participants must normally give their consent in writing (e.g. by signing the **informed consent form** and **information sheets**). If consent cannot be given in writing, for example because of illiteracy, non-written consent must be formally documented and independently witnessed.

In addition, when conducting surveys, interviews or focus groups where personal information is gathered and stored, one must also pay attention to:
– privacy
– data protection
– data management

In order to comply with these requirements, *Many-Me* has developed an informed consent form (see Annex) that has been translated in German, Greek and Dutch respectively. With this form, the research subjects for the interviews during the user requirements' analysis have been approached. All research subjects performing the interviews have been anonymized though the use of codes not disclosing their names or contact details.

5. Conclusions and recommendations

For interviews and surveys during the users' requirements' analysis, the correct measures have been taken through the informed consent form and anonymization of data.

Apart from the end-user organisations who will collect personal data and need informed consent for this, the system developers (technological partners) in *Many-Me* should identify as soon as possible what kind of personal data is needed. Furthermore, in the *Many-Me* quality assurance system, it should be made clear how these data are stored and protected and who monitors this and this concerns not

only the data on national level where every *Many-Me* partner is based, but also on EU level when these data are collected by the coordinator based in the Netherlands.

Ensure that data are kept securely and that publication (including publication on the internet) does not lead (either directly or indirectly) to a breach of agreed confidentiality and anonymity.

If we are collecting personal information, interviewing, observing or tracking people, or recording data or audio/visual information, *Many-Me* needs fully informed consent from our research subjects and we must provide a clear description of the procedures that *Many-Me* will use for data control and anonymisation.

Details should be included into the quality management system of our procedures for data collection, storage, protection, retention, transfer, destruction or re-use (including, collection methodology (digital recording, picture, etc.), methods of storage and exchange (LAN, cloud, etc.), data structure and preservation (encryption, anonymisation, etc.), data-merging or exchange plan, commercial exploitation of data sets, etc.).

Furthermore, details of our data safety procedures (protective measures to avoid unforeseen usage or disclosure, including mosaic effect, i.e. obtaining identification by merging multiple sources) should be described in the quality management system.

Best is to nominate a privacy officer on behalf of the coordinator who introduces a privacy procedure based on the requirements mentioned in this guide and see to it that the consortium follows this.

6. References

Ethics for Researchers; Facilitating Research Excellence in FP7

A publication of the European Commission, Brussels, 2013

http://ec.europa.eu/research/participants/data/ref/fp7/89888/ethics-for-researchers_en.pdf

Ethics Issues table template

A publication of the European Commission, Brussels, Version 1.1., 11 July 2014

http://www.h2020-health.ru/system/tdf/document/ethics-eit_en.pdf?file=1&type=node&id=266&force=

H2020 Programme; Guidance How to complete your ethics self-assessment

A publication of the European Commission, Brussels, Version 5.2, 12 July 2016

http://ec.europa.eu/research/participants/data/ref/h2020/grants_manual/hi/ethics/h2020_hi_ethics-self-assess_en.pdf

Data protection and privacy ethical guidelines

A publication of the European Commission, Brussels, 18th September 2009

http://ec.europa.eu/research/participants/data/ref/fp7/89827/privacy_en.pdf

AAL PROGRAMME

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Annex I Awareness list data protection and privacy issues

Name of partner	
Country	
Role (end-user/research/etc.)	
Contactperson on ethics/data protection	
Email address contactperson	
Tel. contactperson	

Introduction

What follows are 10 questions that need to be answered on data protection and privacy issues[5]. Not all questions can be answered in detail yet, but try to make the best of it. We can conclude that *Many-Me* has to work with humans, collects personal data and involves so called third countries (i.e. non-EU member states, such as Switzerland). Some of the questions below relate to this.

Apart from the end-users who will collect personal data and need informed consent for this, the developers should identify as soon as possible what kind of personal data are needed. Furthermore, in the *Many-Me* quality assurance system, it should be made clear how these data are stored and protected and who monitors this.

Basically, the questions below will define the content and related paragraphs of the *Many-Me* Ethics guidelines. Therefore, your first answers are crucial.

A more concise explanation on how we can deal with these three core issues, namely: 'human beings', 'personal data' and 'non-EU countries' is given in Guidance How to complete your ethics self-assessment. If interested, have a look at it to understand the scope of the issues we are dealing with it. Clearly, what is described here, will also form elements of the *Many-Me* training on ethics/data protection.

Questions

1 – Will any type of personal data be used and/or stored within the framework of the research?
If Yes, move to question 2

2 - What kind of human participants/data are involved within the research?

[5] Source: Data protection and privacy issues ethical guidelines, EU Experts Working Group on data protection and privacy, 18-09-2009

2.1 - categories of human participants
- Patients/clients
- Formal/informal careproviders
- Healthy volunteers (related to health research)
- Volunteers (for surveys, etc…)
- Workers' (e.g.: research lab personnel…)
- Participating researchers' list
- Children
- Vulnerable adults
- Others…..special population groups? Developing countries? etc.

Try to provide an answer:	…

2.2 - categories of data used
- Previously collected data (their sources and usage history)

The content of the data set needs to be specified and copies of appropriate authorizations need to be provided according to the legal requirements of the area where the research is planned to take place.

Try to provide an answer:	…
What is the appropriate ethics authority in your country you need approval of?	…

3 – Are all sensitive data that are planned to be collected really focused on the research question and is relevant for the foreseeable research?

We will need to explain the reasons behind the proposed data collection: Data from different sources should not be amalgamated without making sure that this action is legally possible, especially in cases where a data set might contain information that identifies individuals and information

Try to provide an answer:	…

4 – For how long will the collected data be used?
Usage times need to be specified. On a general point of view, data must be specifically stored solely for as long as the project lasts. Data usage beyond the life of the project is possible but must be closely supervised.

Try to provide an answer:	…

5 – For how long will the collected data be stored and when will it be irreversibly destroyed?
Conservation times need to be specified. Destruction methods need to be illustrated. The costs for both options need to be taken into account when estimating the project's final budget.

Try to provide an answer:	…

6 – Do we (all partners) have the necessary legal permission to obtain and process the data? If data are directly gathered from individual research participants, is the planned informed consent system effective?
Informed consent for the proposed project will be required, even if personal data has been collected in the frame of previous research projects: If data from a previously gathered set - either by *Many-Me* or from another project or person – are used, does the initial informed consent cover this complementary use of the data, or does the partner have to obtain a completely new informed consent for the proposed research. The partners need to discuss these options along with their national/local data protection agency.

Try to provide an answer:	…
What is the appropriate ethics authority in your country you need approval of?	…
Would you have an example of an eligible 'informed consent' form used before?	…

7 - How will the collected personal data be securely accessed?
Secured access policy needs to be worked out and clearly specified. It needs to be proportional to the risks involved and the sensitivity of the data, and must clearly state the type of processes - such as password protection, encryption, "need to know basis" principles (i.e.: only the users that need to access the data will be allowed to do so), - that will be implemented.

Try to provide an answer:	…

8 – How will the data be securely stored: data structure and format?
Data structures such as databases need to be specified - if applicable, it should be specified that identification data will be encrypted and strictly separated from sensitive data such as health data – It should also be specified how the unforeseen data added during the research, such as incidental findings, will be treated.

Try to provide an answer:	…

9 – How will the data be securely stored: location & hardware?
Conservation methods need to be specified. A non-WAN connected computer server or HARD disk should be preferred. Data should not be stored on a memory stick or other easily lost/accessed media.

Try to provide an answer:	…

10 – How will data transfer be monitored?
Transfer of data outside the EU needs to be identified and specified. The handling process should be specified. Data transfer (between whom and whom) within the project, especially with partners from non-EU countries (developed and/or developing countries) must be given special care due to the variety of legal and administrative standards, bearing into mind that compliance with the relevant EU rules and international/bilateral agreements incorporated into EU law is compulsory. This is because EU legislation requires that the transfer of data outside Europe to be undertaken only to places where there is a local assurance by the proper legal authorities that the level of data protection is at least equivalent to that of the EU area. We need to consider this aspect not only between

institutions and companies and the like, but also within companies and the research partnership across geographical borders.

Try to provide an answer:	…

Annex II Informed Consent Form

INFORMED CONSENT

Title of the Project:	*Many-Me*
Website:	**http://many-me.eu/**
Coordinator:	Drimpy
Leading Local Investigator:	>Name of the Local Investigator<
Institution:	>Name of the Institution<
Financed by:	>Name of the national funding Organization<
Programme:	AAL Joint Programme (AAL JP) **http://www.aal-europe.eu/**
Call:	Call AAL-2016 – Living well with dementia
Project Number:	**Project Type:** Cooperative Project
Project Duration:	36 Months
Project Start - End:	1st March 2017 – 1st March 2020

The study described in this document is part of the research project 'Social Interactive Care System to support the wellbeing of people living with dementia'. Proposal acronym: *Many-Me*. The European Union (EU) and the >**Local funding Organization**< finance this project under the AAL Joint Programme (Project number: AAL-2016-3-063).

This informed consent document may include words that you may not understand. If that is the case, please ask the research contact person or any other staff of the study to fully explain the meaning of the words or piece of information you do not understand. You may take a copy of this consent to think about it or talk to your family and friends before making any decision. At all times, we assure the compliance to the current legislation.

I. INTRODUCTION

You have been invited to take part in a research study of the *Many-Me* project. Before making a decision on whether you want to participate or not, please read this document carefully. Please ask all the questions you may have so you can be completely sure that you understand the scope and procedure of the study, including risks and benefits.

II. PURPOSE OF THE STUDY/PROJECT

The general objective of the *Many-Me* project is to develop a social interactive care system based on ICT, in order to offer early stage dementia patients, support to cope with the disease and live an active and meaningful life. Our solution will be co-created together with early stage dementia patients and their caregivers, optimised and customised to their specific needs.

The main goal is the development of easy to use, intuitive interfaces and familiar devices, we offer primary end-users, like you, means and support to stay active and independent, keep their habits,

adopt helpful routines, connect with peers and make friends. The system will also provide safety for outdoor activities, permanent monitoring capabilities and it acts as an emergency system when necessary.

Caregivers (formal and informal) will have access to networking, education and training, so they can learn effective ways to provide care and reduce their burden. The system recommends care giving activities based on profiles and context. It also allows close monitoring of patient care plans with input from informal caregivers, automatic notifications and guidance to help patients stay healthy and perform activities of daily living.

Our mission is to build and bring to market this unified system, making it available for every EU citizen to improve their health and wellbeing. From the six different countries (Switzerland, Austria, The Netherlands, Cyprus, Romania and Poland) that form the project consortium, four will test the solution and will help us develop a ready to market product that can be applicable in every EU country.

III. PARTICIPANTS IN THE STUDY AND POSSIBLE PARTICIPATION

We kindly request your voluntary participation in this research project. This informed consent includes information on the research project. We would like to assure that you are perfectly informed about the purpose of the study and what your participation in it implies.

Please ask to clarify any section in this information document you do not understand. Please, do not sign, if you are not sure that you have understood all the aspects of the project and its objectives. The participation in this project is totally voluntary and you will not have any financial burden. You can withdraw at any moment without being penalized.

The criteria for participating in this study are as following:

- being an older person (>50 years) suffering from a mild cognitive impairment (MCI) and living independently
- being a family member or caregiver of an older person (>50 years) suffering from mild cognitive impairment (MCI)

IV. PROCEEDINGS:

Within the *Many-Me* project the above-mentioned users will be invited to think of requirements, lab and field trial studies of the developed system prototypes. Within these studies, you will have the chance to give information on necessary requirements, needs and wishes in early project phases. In further project phases, you have the chance to try the prototypes (lab trials, field trials) and give feedback concerning usability and user experience that will be used to refine and enhance the system. Participants will have to perform specific tasks related to the prototype as well as to answer questionnaires and partake in interviews regarding user experience and usability aspects of the system. Some activities will be audio and video recorded for backup and analysis reasons. After the project, when all testing is finished, the participants are allowed to keep on using the Many-Me services if they wish.

V. RISKS OR INCONVENIENCE

The potential risks that may arise from participating in the program are:

- Replacing your doctor's advice and guidance with the *Many-Me* application. This application cannot and should not replace the doctor's advice and guidance.
- Participants may develop the feeling of dependence towards the application. At the end of the project the usability of the application will be assessed; there is a possibility that this application might be considered inappropriate or unsuitable. Therefore, the devices will have to be returned; this may cause insecurity or anxiety to participants. In such case the participants will be referred for support to a specialist.
- During trial periods, participants may feel anxiety due to the exposure and adaption to the devices. The project team will provide support to participants so as to use the devices and adapt to the new conditions.

VI. BENEFITS

Participants will have the opportunity to meet people with the same diagnosis and to join support groups that will help to empower them. They will have the opportunity to test and adopt techniques to help their memory and cognitive function. Additionally, through the on-line platform, which will be designed with their own contribution, based on their needs, they will be provided with advice on health issues and information tailored to their needs. In addition, through the platform along with the project team's support, they will be empowered in order to increase the degree of self-management of their situation.

The direct benefit for participants with moderate cognitive impairment will be the provision of a personalised care programme via the online platform where the community (informal carers, family members, health professionals, and friends) will be involved in critical situations. The platform will provide an alert system to support participants in situations that increased security, autonomy, and more involvement in activities with other people may be required.

The personal benefit from participating in any activity of the *Many-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 life-style. 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.

VII. PRIVACY AND CONFIDENTIALITY

Your registered and/or recorded responses will not include any personal identification information. Hence, it will not be possible to identify you after your participation in any study. Recorded information will be processed during the phase of data analysis and will be included in project internal reports or later in scientific publications. It will not be possible to identify the source of the information.

The results of this study may be published in scientific magazines, conference proceedings or books. Complete anonymity of personal data is guaranteed by the *Many-Me* partners.

The authorization for the use of and access to your anonymised data is completely voluntary. This authorization is valid until the end of the study. If you should decide to deny 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 under VIII.

From the moment, you withdraw from the *Many-Me* project, your data will not be used in any further phase of the project. However, documents that have already been published or are part of the study that have been finished will not be able to be altered.

Your decision to whether or not give your authorization for the use and diffusion of the information provided by you is completely voluntary. However, 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.

VIII. CONTACT PERSONS

For further information about your rights as a participant in the investigation, 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 investigation, please contact the leading investigator:

>Name of the Local Investigator<
>Name of the Local Institution <
>Street<
>Building<
>Postal Code and City<
>Country<
>Telephone Number of Local Investigator<
>Mail Address of Local Investigator<

IX. PHOTO, VIDEO AND AUDIO RECORDING

As part of this research project, photograph, videotape and audiotape recordings during the participation in the study will be done.

I have received a thorough description of the purpose and procedures for any recordings and I give my consent to allow >Name of the Local Institution< use the recordings or parts of the recordings for analysis, related studies and project results, as well as for marketing and PR purposes of *Many-Me.* I understand that all information will be kept confidential and will be reported in an anonymous way.

X. CONFIRMATON

Your participation in this study is only possible if you freely and independently sign this consent to authorize us to use the data you provide. If you do not wish to do so, please do not subscribe and do not participate in this study.

I have read the information in this informed consent document or the information has been read to me in an adequate way. All of my questions about the study and my participation in it have been answered.

Mark one of the following:
☐ I read all the information in this form.
☐ The information in this informed consent was read to me by:

…….

☐ All the questions that I had, have been answered by:

……

I authorize the use and analysis of my answers to the entity aforementioned for the purposes above indicated. Signing this informed consent does not imply giving up to any legal rights. I accept in a voluntary way to participate in this investigation carried out by >Name of the Local Institution< and the rest of the partners of the *Many-Me* Project. I understand that I have the right of having a copy of this informed consent. Therefore, a copy will be provided to me.

Name and surname of the participant:
……

Date:
……

Signature of the participant
……

Name and surname of the researcher
……

Date:
……

Signature of the researcher:
……

The project *Many-Me* is funded under the AAL Programme 2016 Call 'Living well with dementia'