**MY-AHA**
Contract # 689592

# My-AHA

**Deliverable 1.5**

## Code of Conduct

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***Abstract***

The Code of Conduct provides a comprehensive framework for good research conduct and the governance of all research carried out during the development of the Horizon 2020 my-AHA project. The Code underpins the commitment to maintaining the highest standards of integrity, rigour and excellence in all aspects of our research and for all research to be conducted according to the appropriate ethical, legal and professional frameworks and standards. The Code outlines the duty of researchers including their responsibilities towards all participants and subjects of research, and it provides a basis for the transparent and appropriate communication and dissemination of research findings.

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# Executive summary

This Code of Conduct provides a comprehensive framework for good research conduct and the governance of all research carried out during the development of H2020 my-AHA project. The Code underpins the commitment to maintaining the highest standards of integrity, rigour and excellence in all aspects of our research and for all research to be conducted according to the appropriate ethical, legal and professional frameworks and standards. The Code outlines the duty of researchers including their responsibilities towards all participants and subjects of research, and it provides a basis for the transparent and appropriate communication and dissemination of research findings. My-AHA welcomes the national frameworks for good research conduct and governance. We will monitor and, where necessary, improve the Code in order to further strengthen the integrity of research carried out. This Code of Conduct finally outlines the ethical guidelines for the research and system development activities in the my-AHA project. Ethics in the context of the my-AHA project is about ensuring the dignity, rights, safety and well-being of research participants and of the users of technology.

A special section of this deliverable is dedicated to the Data Management, to be performed in accordance with the new Regulation of the EC. To follow this regulation, a data management officer will be nominated.

Finally, this code of conduct establishes some general rules on the publication policy of the Consortium and on the inclusion of researchers in the authors' list.

# List of authors

| Company | Author |
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| UNITO | A. Vercelli, C.Abrescia, F.Rioli |
| USC | M. Summers |

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# List of figures and/or list of tables

No figures and tables.

# Abbreviations

A list of abbreviations is strongly recommended

CA consortium agreement

GA grant agreement

IADL Instrumental Activities of Daily Living

OECD Organisation for Economic Co-operation and Development

UD universal design

UX user experience

# 1 Document scope

This Code of Conduct provides a comprehensive framework for good research conduct and the governance of all research carried out during the development of the Horizon 2020 my-AHA project. The Code underpins the commitment to maintaining the highest standards of integrity, rigour and excellence in all aspects of our research and for all research to be conducted according to the appropriate ethical, legal and professional frameworks and standards. The Code outlines the duty of researchers including their responsibilities towards all participants and subjects of research, and it provides a basis for the transparent and appropriate communication and dissemination of research findings. My-AHA welcomes the national frameworks for good research conduct and governance. We will monitor and, where necessary, improve the Code in order to further strengthen the integrity of research carried out. This Code of Conduct finally outlines the ethical guidelines for the research and system development activities in the my-AHA project. Ethics in the context of the my-AHA project is about ensuring the dignity, rights, safety and well-being of research participants and of the users of technology.

# 2 To whom, and to what, does the Code apply?

The Code applies to all employees, students, visiting and emeritus researchers involved in my-AHA, whether they are working on the premises of the partners of the consortium or elsewhere.

The Code applies to all research deliverables and outputs in whatever form, and to all research activity.

# 3 Research conduct

All persons and institutions involved in the my-AHA research project owe a duty of accountability to society, to their profession, to all participants in the research and to the EC. Staff must accept full responsibility for their own conduct of their research and the activities of all staff, students and others under their direction or supervision.

Researchers must be honest and lawful in respect of their own actions in research and in their responses to the actions of other researchers. This applies to the whole range of research work, outputs and deliverables, including: experimental design; generating and analysing data; publishing results; and, acknowledging the direct and indirect contribution of colleagues, collaborators and others. Plagiarism, deception or the fabrication or falsification of results shall be regarded as research misconduct and a serious disciplinary offence. Researchers should declare and manage any real or potential conflicts of interest.

## 3.1 The ethical basis and design of my-AHA research project.

Researchers must ensure that my-AHA project is ethically sound and have received the approval of the relevant ethics committee(s) and all relevant statutory regulatory authorities before they commence.

## 3.2 Safety

The safety of all involved in the research process, ensuring that the research is carried out in accordance with health and safety policies and legislative requirements must be guaranteed. Research must be conducted in a suitable working environment with appropriate equipment and facilities.

## 3.3 Management of research data

Management of research data will be performed in accordance with any other legal provisions, conditions and guidelines that may apply to the handling of personal information (see below); in particular, it will be dealt in agreement with the Regulation 2016/679, effective from 2018. As requested by this regulation, a **Data Protection Officer** will be selected.

## 3.4 Standards

My-AHA will ensure that all personal records of research progress, including authorised laboratory books, are maintained to the recommended or required standards, and that the falsification of results does not occur. Laboratory books must be signed and dated by the researcher, and signed off by the supervisor.

My-AHA will ensure confidentiality in order to achieve protection of intellectual property rights where appropriate.

My-AHA will ensure that research findings are suitably disseminated.

My-AHA will ensure that research subjects participate in a voluntary way, free from any coercion, and will avoid harm to participants and minimise any adverse effect that the research may have on people and the natural environment and property.

# 4 Overview of the my-AHA project

## 4.1 Challenges and solutions

Physical impairment is the main hallmark of frailty; however, emerging evidence suggests that other dimensions, such as psychological, cognitive and social, also contribute to this multidimensional condition. Cognition is now considered a core domain of frailty. Cognitive and physical frailties interact with each other: cognitive problems and dementia are more prevalent in physically frail individuals, and those with cognitive impairment are more prone to become frail. Finally, social frailty is significantly associated with disease outcome and mortality risk. In current clinical practice, a number of measures assessing risk of physical and cognitive frailty are in use for early screening and intervention of frailty, including biomarkers (APOE4, inflammatory markers, Vitamin D, etc.), clinical measures (MMSE, GDS, gait, weight, strength, balance, etc.), as well as imaging (MRI, CT, etc.). Despite a good clinical evidence as "single shot" screening tests, evidence indicates that the majority of these measures lack sufficient sensitivity to detect very early and small changes in the risk factors required to enable appropriate prevention of associated diseases, like dementia, sarcopenia or falls in later life. Despite this, there has been a recent emergence of technological solutions to support active ageing and tackle frailty, cognitive decline and social isolation of older adults.

While ICT-based solutions are of a certain value regarding diminishing single risks (e.g. fall risk, etc.), there is still a need for a more holistic approach to address a combination of multiple individual risk factors for frailty. Further, having identified a multidimensional risk for frailty in the individual it is then necessary to provide tailored interventions to prevent onset of frailty in those persons identified as being at high risk for later frailty in the risk analysis.

This development of a multidimensional risk analysis and intervention platform is the main objective of my-AHA project. The my-AHA project aims to develop and implement an ICT-based solution for early risk detection and intervention (i.e. prevention), in order to support active and healthy ageing and prevent cognitive impairment, frailty, depression and falls by unobtrusive behavioural sensing, based on large scale collection of data, readily available in the daily living environment of older adults. My-AHA solution supports active and healthy ageing by enabling early detection and minimization of risks associated with ageing, and in particular for Dementia (MCI), Depression (Mood), Falls and Frailty. In these terms the early risk detection considers three fundamental aspects of the life of older adults, physical activities (by considering vital data, gait, quality of sleep and in general, movements activities, and fall risk), cognitive activities (by monitor the cognitive level, e.g. in exergames) and social activities (e.g. by analyzing the emotions and the quality of speech of the users). On the other hand, my-AHA designs and implements more efficient and effective ICT-based interventions tailored to the early identified risks, by integrating innovative ICT solutions and involving the stakeholders. The suggested social activities, as well as cognitive and physical trainings and the diet proposed to the older adults via the new platform will help the users in changing their behaviour sustainably and in reacting to the consequences of ageing.

## 4.2 Target groups

The target groups for the my-AHA system are:

1) Primary end-users: older adults.
2) Secondary end-users: informal and/or formal carers.
3) Service providers, insurers, doctors.

The system outlined here provides a platform incl. infrastructure for promotion or use of new services for all relevant stakeholders in the active and healthy ageing market. These are the representatives of various interest groups - health and related insurance, doctors and clinics, medical service providers, technology and software vendors. The service platform enables service providers (incling medical service providers,

 

equipment manufacturers, intervention vendors, etc.) to offer services that can make use of existing infrastructure and new contents and data. The services involve all stakeholders (insurance, medical services, physicians, and patients). The platform offers the possibility of linking through the information of all stakeholders. The platform enables the participants to take the server vices for themselves and/or the patient to complete and allows for use of other users of the data, with the patient to take control regarding the transfer and use of his/her own data, and where to keep it.

## 4.3 Technology

The my-AHA system will use sensing technologies and smart devices, e.g., smart phones or tablets. My-AHA will make use of commercial and non-stigmatizing devices (smartphones, unobtrusive glasses, portable medical devices, MS-Kinect, etc.) to collect data from all frailty domains and to allow a robust detection of pre-frailty and frailty situations.

## 4.4 Business model

The overall aim is to establish a social business model to carry on the financing of the go to market phase after the project. These commitments will be confirmed during the last phase of the project to ensure the future market development. Social investors will be included in early discussion processes. Providing a social business plan gives the opportunity to create new opportunities outside of a private, capitalist approach that is driven by personal profit. The benefit of a social initiative and associated business models is oriented towards society. Through this, sustainability is ensured as the beneficiary parties are well spread across various demographic spectra. Profit is not maximised but secured. The market evolution points directly to a new health model founded by self-management and personal adherence by patients. As physicians are becoming service stations and hospitals increasingly become intervention centres; the patient empowerment is an unstoppable process in a knowledge centric society.

***Public-Private-Partnerships*** - Another important objective of project exploitation is to contribute to the initiation of a new area of business in the field of ICT and active and healthy aging, especially for SME. The project seeks to contribute to social and technical innovation: new products, services, and models that simultaneously meet the needs of older adults more effectively than alternatives and create new Public-Private-Partnerships or similar collaborations. We expect to create something new in the field of ICT for Active and Healthy Ageing, and thus foster new businesses for entrepreneurs (SMEs) and social service suppliers (start-ups or welfare organizations). Health and prevention services and products have reached an individualised level. “Off-the-shelf” products such as vital data trackers, game consoles, sensor devices such as the Kinect from Microsoft lessen the challenges of hardware/software development for specific products so that developers and designers can concentrate on creating a superior solutions. Thus, the new my-AHA platform will be developed to provide an open and modular innovation system for further deployment of active and healthy ageing related ICT-based services such as new risk assessment algorithms and tailored intervention programs. This has the potential to reduce start-up costs if only being used by a small proportion of the target population. The real potential however are the opportunities that the open architecture of my-AHA enables to develop or combine existing solutions with new platforms, devices and contents, e.g. for cancers or cardiopulmonary diseases. A system like my-AHA using validated components and exercises like OTAGO or ADL (activities of daily living) open up new possibilities for research and development, whereby the time to market for customers to buy and engage with new active ageing or fall prevention solutions is considerably lower based on:

- A modular system, ready to take up other ICT solutions, exergames and training exercises for different syndromes and diseases
- exchangeable hardware/software components such as skeleton/movement detection with Kinect
- lowered problems with hardware service and maintenance because existing support systems are already in place from the technology manufacturers throughout Europe
- building-up of a health and active ageing related “European App-Store” through which other funded projects and initiatives like EIP-AHA or others will be able to sell their software/hardware and/or interventions to the installed my-AHA framework. For example, there are many successful and interesting projects in universities or SME projects, but they lack the opportunity to come to the market easily. The combination of already existing modules such as vital data integration from mass

market devices like step trackers or similar products of successful players in the market such as Medisana, VitalinQ, JIN's MEME, etc. will allow lower prices and opens up potential partnerships of SMEs for bringing the my-AHA solution more successful to the market.

In my-AHA, the modular design of the new software components and its unique architecture based on international standards will provide a solution that allows for new exercises or sensor implementations as additional "off-the-shelf" modules for other projects. This will decrease the time and costs to market for additional software solutions from new SME partners or research demonstrators (e.g. iStoppFalls, Smart Companion) significantly.

## 4.5 End-user participation

End-users will participate throughout the project being invited to interviews, focus groups and field trials and will contribute to the development of the user requirements, technology and/or system testing, to field trials and assessment of IADL support, carer stress and quality of life (QoL). Ethical issues have a prominent role through the dedicated work package WP7. Furthermore, the release of promotional material will make end-users and caregivers aware of the project and make it easier to enlarge the sample size in the exploitation and scale-up phases. Additionally, workshops and public meetings will be organized with the scope to educate, create awareness and involved members from different institutions, associations etc. to the project, with a twofold objective: 1) to create strategic partnerships, useful for the exploitation and commercialization steps; and 2) to publicize and show to a wide public the value of services and the results obtained during my-AHA project. Finally, a sophisticated social media outreach strategy will be developed and implemented. This will target key influencers in the ongoing public discussions on health and specifically aging; as well as reaching out to other influential institutions, research institutions and even health insurance bodies with an interest in active and healthy ageing. Additional targets will be the families of older adults as a secondary opportunity to extend the marketing opportunity afforded by social media.

 

# 5 Code of conduct for my-AHA research activities

## 5.1 RESPECT Code of Practice

The my-AHA project consortium have agreed to conform to the **RESPECT** Code of Practice, originally developed as a framework for the conduct of ethical socio-economic research in Europe. The RESPECT code of practice is based on three main principles:

1. upholding scientific standards,
2. compliance with the law, and
3. avoidance of social and personal harm.

### 5.1.1 Upholding scientific standards

Colleagues planning and conducting research and disseminating research findings must strive to do so with integrity, honesty, objectivity, accuracy, inclusiveness, and clarity.

See the RESPECT Code of Practice at http://www.respectproject.org/code/respect_code.pdf for further details.

### 5.1.2 Compliance with the law (and regulatory systems)

Colleagues in each country need to ensure that they comply with any relevant regulations, both European and those applicable specifically within an individual country (for example in Europe the DU Data Protection Directive 1995, the Regulation 2016/679 and in the UK the Mental Capacity Act 2005 and the Data Protection Act 1998).

#### 5.1.2.1 Data protection

The European Union issued an EU Data Protection Directive in 1995. More recently EU issued another directive in April 2016, repealing Directive 1995/46: regulation shall apply from 25 May 2018.

#### 5.1.2.2 Gaining ethics approval for research projects

Colleagues also need to ensure that they comply with any relevant ethics approval systems (academic, local and/or national):

**Each my-AHA participating country is responsible for applying for any relevant ethical approval.**

### 5.1.3 Avoidance of social and personal harm

Colleagues planning and conducting research activities for the project need to ensure that:

- the research is designed appropriately so that its utility and relevance for the benefit to society is maximised;
- people participating in the research do so on a voluntary basis and on the basis of informed consent;
- the research methodology is suited to the participants and no one is unreasonably excluded from being able to take part;
- information is communicated clearly and in an appropriate way (or ways) for the target audience;
- the views of all relevant stakeholders are taken into account as long as this is not in opposition with other ethical or scientific principles;

- the interests of participants are given high priority at all times especially those of vulnerable groups such as older people;
- participants do not experience unwarranted material gain or loss through their involvement in the research;
- findings from the research are disseminated to stakeholders in relevant and accessible formats;
- no group is discriminated against;
- participants are protected from undue risk of distress, personal embarrassment, indignity, intrusion, and psychological, social or physical harm;
- the safety and wellbeing of researchers is also given high priority.

# 6 Data Protection Directive

Distinction shall be drawn between personal and research data. Personal data is any data by which possession of could identify an individual. Research data are the metrics collected as part of the research and solely by which an individual cannot be identified. Personal data may also be research data. All processing of personal data (which includes the obtaining and storage of data) must comply with the terms of the EU Data Protection Directive 1995/46/EC (to be replaced from May 2018 by the Regulation 2016/679) and of the Data Protection Act 1998 (http://www.legislation.gov.uk/ukpga/1998/29/contents). It is recommended that researchers familiarise themselves with published guidance which interprets the application of the Act and any other relevant legislation that is pertinent to specific fields of research.

## 6.1 Some central issues for researchers are:

### 6.1.1 Personal data

- All staff and students using personal data in research have a duty of confidence to the individuals concerned;
- Unless there are ethically and legally justified reasons for doing otherwise, researchers must ensure that they have each study participant's explicit informed written consent to obtain, hold and use their personal information;
- Only personal information pertinent to the research should be collected;
- Data security arrangements must be sufficient to prevent unauthorised breaches of confidentiality;
- Personal data should not be kept for longer than is necessary.

### 6.1.2 Research data

- Data must be recorded in a durable form with appropriate references;
- Data must be retained intact for a period of at least ten (10) years from the date of any publication which is based upon them. Data should be stored in their original form – i.e. tapes/discs etc should not be deleted and reused, but kept securely as outlined.
- Confidentiality provisions relating to publications may apply in circumstances where the researcher has made or given confidentiality undertakings to third parties or confidentiality is required to protect intellectual property rights. It is the obligation of the research leader to inform researchers as to whether confidentiality provisions apply and of researchers to enquire of their research leader whether there are any obligations with respect to these provisions

### 6.1.3 Sensitive data

"Sensitive personal data" means personal data consisting of information as to:

- the racial or ethnic origin of the data subject;
- political opinions;
- religious beliefs or other beliefs of a similar nature;
- physical or mental health or condition;
- sexual life;
- the commission or alleged commission by the data subject of any offence; or
- any proceedings for any offence committed or alleged to have been committed by the data subject, the disposal of such proceedings or the sentence of any court in such proceedings.

All my-AHA partners must comply with the EU Data Protection Directive, and any additional national data protection regulations in their own countries.

The information in this section is taken from the European Commission website:

http://ec.europa.eu/justice/data-protection/data-collection/obligations/index_en.htm

Under EU law, personal data can only be gathered legally under strict conditions, for a legitimate purpose. Furthermore, persons or organizations which collect and manage personal information must protect it from misuse and must respect certain rights of the data owners which are guaranteed by EU law.

## 6.2 Collecting and processing personal data: what is legal?

Under the Data Protection Directive 1995, collecting and processing the personal data of individuals is legitimate only in one of the following circumstances laid down by Article 7 of the Directive:

- **Where the individual concerned, the 'data subject', has unambiguously given his or her consent, after being adequately informed**; or
- if data processing is needed for a contract, for example, for billing, a job application or a loan request; or
- if processing is required by a legal obligation; or
- if processing is necessary in order to protect the vital interest of the data subject, for example, processing of medical data of a victim of a car accident; or
- if processing is necessary to perform tasks of public interests or tasks carried out by government, tax authorities, the police or other public bodies; or
- if the data controller or a third party has a legitimate interest in doing so, so long as this interest does affect the interests of the data subject, or infringe on his or her fundamental rights, in particular the right to privacy. This provision establishes the need to strike a reasonable balance between the data controllers' business interests and the privacy of data subjects.

It shall be noted that Article 8 prohibits the processing of personal data revealing racial or ethnic origin, political opinions, religious or philosophical beliefs, trade-union membership, and the processing of data concerning health or sex life unless one of the exception criteria is met.

## 6.3 Obligations of data controllers

The Data Protection Directive requires data controllers to observe a number of principles when they process personal data. These principles not only protect the rights of those about whom the data is collected ("data subjects") but also reflect good business practices that contribute to reliable and efficient data processing.

Each “data controller” (e.g. persons or entities which collect and process personal data) must respect the following rules as set out in the Directive:

- Personal Data must be processed legally and fairly;
- It must be collected for explicit and legitimate purposes and used accordingly
- It must be adequate, relevant and not excessive in relation to the purposes for which it is collected and/or further processed;
- It must be accurate, and updated where necessary;
- Data controllers must ensure that data subjects can rectify, remove or block incorrect data about themselves;
- Data that identifies individuals (personal data) must not be kept any longer than strictly necessary;
- Data controllers must protect personal data against accidental or unlawful destruction, loss, alteration and disclosure, particularly when processing involves data transmission over networks. They shall implement the appropriate security measures;

 

- These protection measures must ensure a level of protection appropriate to the data.

### 6.3.1 Responsibilities towards data subjects

If a data subject is of the view that their data has been compromised (e.g. collected or processed illegally, inaccurately, or misused), they can send a complaint to the data controller. If the data controller's handling of a complaint is not satisfactory, the data subject can file a complaint to the national supervisory data protection authority (see below).

### 6.3.2 Confidentiality

Individual participant personal information obtained as a result of research is to be considered confidential and disclosure to third parties is prohibited with the exception of statutory notification as applicable to the particular research. Participant confidentiality should be ensured by utilising identification code numbers to correspond to research data in any research paperwork and computer files.

### 6.3.3 National supervisory authorities for each country

The Directive states that every EU country must provide one or more independent supervisory authorities to monitor its application. All my-AHA participating countries must contact their supervisory authority. Contact details for all European countries can be found:

http://ec.europa.eu/justice/data-protection/bodies/authorities/

In principle, all data controllers must notify their supervisory authorities when they process personal data.

# 7 Ethics and the development of assistive technology

## 7.1 Horizon2020 and AAL Programme guidance

Some ethical aspects of my-AHA project are already considered in the AAL programme.

Annex 3 of the Guide for Applicants of the Ambient Assisted Living Program states:

"The nature of the projects will raise a broad range of ethical concerns as:

- the technology involved is often new and unfamiliar to the end-users,
- vital aspects of the solutions will not be transparent to the end-users and other stakeholders because of a high degree of complexity.

Solutions developed must be trusted, accessible and accepted by all designated user groups.

Ethics in the context of H2020 projects is fundamentally about what a project can and shall do for the benefit of those defined as the end-users of that particular project. Ethical issues may also be raised regarding the relationships and social networks of the involved (or future) end-users. New solutions might bring about new allocation of resources and responsibilities and thus have an impact that goes beyond the quality of life of primary end-users.

In the conduct of an H2020 project, ethical issues concern inter alia the correct recruitment and involvement of end-users."

## 7.2 Common principles

Researchers developing assistive technologies commonly use the following four principles identified by Beauchamp and Childress (2002) to guide their decisions and solutions: Beneficence, Non-maleficence, Autonomy, and Justice. The Telecare and Ethics factsheet from the UK Care Services Improvement Partnership (2005) defines each of these:

1. Beneficence (do good): involves finding the balance between risk tolerance and risk aversion. There may be a dilemma between beneficence and safety and independence.
2. Non-maleficence (do not harm): will involve a balance between avoiding harm and respecting decisions, dignity, integrity and preferences.
3. Autonomy: enabling people to live full lives in the same way as they did before, which may be more about promoting continuity of self rather than about making decisions. This should include informed consent, which needs to be voluntary, competent and include sufficient information. Carers may need to help/guide in this process.
4. Justice: treating fairly and respecting rights, including what the Mental Capacity Act calls making "eccentric or unwise decisions" (Mental Capacity Act, 2005).

 

# 8 Applying codes, regulations and guidelines to specific areas of the my-AHA research activity

Ethical and legal issues as described in the my-AHA proposal document are presented in Appendix 1.

## 8.1 Privacy (data protection)

After confirmation of the participant's wish to take part (informed consent), all personal data (name, address, contact information etc.) must be stored safely and securely where no unauthorised person can gain access to it. No personal information provided by participants will be disclosed to a third party without the explicit consent of the participant concerned.

Each individual participant must be assigned an identification number. This identification number should then be used on interview sheets, questionnaires etc. instead of the person's name or address so that the information gathered is anonymous. This information must be stored separately from their personal data (name, address, etc.). Databases linking personal information with code numbers should be password protected. The possibility of encrypting databases (or communication between user and databases), and which encryption standard to be used, will be discussed internally.

### 8.1.1 Social media

Researchers and carers must be very careful when sharing any material through the my-AHA social media, whether this be opinions, experiences, or video clips. It is not appropriate to make public reference to the older person's cognitive problems as this is private health information. It is also not appropriate to indirectly share any private health information, or any other personal information, without informed consent of the primary user.

Example:

Appropriate advice to carers must be provided to them during the project tests and trials. Useful tips must be developed and made easily available for and through the social network of the my-AHA system.

## 8.2 Informed consent

All participants taking part in the focus groups or trials of the my-AHA project will be asked to complete an "Informed Consent Form". Informed consent must be given based upon a clear appreciation and understanding of the facts, implications, and future consequences of participation in the my-AHA project. This will include the provision of clear and easy to understand information sheets.

In order to give informed consent, the individual participant must have the capacity to give consent as determined by possessing adequate reasoning faculties and be in possession of all relevant facts at the time consent is given.

Care must be taken to ensure all participants, both the end-user and carer, are taking part willingly and are not coerced or induced to do so (for example a carer might convince the user to take part as he/she feels it would help him/her).

Consent will be re-established verbally at the beginning of any subsequent meeting or interviews during the trials to make sure that participants still wish to take part. Participants will be free to leave the project at any time. It is good practice for the consent procedure to be seen as a process rather than a one-off event, with individuals being given information about the project on a repeated basis and having the opportunity to withdraw as they wish.

Informed-consent forms should guarantee transparency and should cover the following issues:

- a description of the project and its aims (accessible with respect to language and content),
- a specification of the role(s) of different end-users in the project,
- self-determination of the end-users (must be able to turn off systems or services at their own discretion),

- contact person in the project (for ethical issues and related questions),
- exit rights for individual end-users (procedure for withdrawal from the project at any time, without giving a reason and without incurring costs or penalties).

The forms for informed consent in the my-AHA project will be prepared for in the frame of WP7 and adapted to the local ethical committees of the partners involved in the trials.

## 8.3 Autonomy of participants

### 8.3.1 Convenient times

All appointments with participants for interviews must be at a date and time convenient for the participant, not for the interviewer.

### 8.3.2 Entitlement to quit

Every trial participant must be allowed to terminate the interviews, focus groups and trials at any time without giving a reason.

### 8.3.3 Exit strategy for field trials

The my-AHA project proposal outlined actions to be taken if participants leave field trials before the full term has been completed. It also proposed the strategy to be taken at the end of the project to address impact of the possible termination of the my-AHA system and service which could cause problems to participants if they have become used to, and possibly reliant on, it.

In case of early exit, the my-AHA equipment (sensors, smartphones, tablets etc.) will be returned to the project. Eventually, the equipment shall be returned to the partner that provided it.

All test and trial participants (primary and secondary end-users) will be informed about their right to exit the project at any time during the on-going user tests or field trials. In these cases, the researchers will to debrief each individual exiting user. This will give us knowledge about how users view the situation and what possible problems might arise in the future. The users will, for quality assurance reasons, be asked for the reason of exit. It will be made clear that there is no obligation to give an answer. To avoid situations in which the secondary end-user wants to exit the project (leaving the primary end-user in a tricky situation), information about possible consequences will be provided to the secondary end users before the trials.

## 8.4 Integrity and dignity

All researchers must respect the participant's needs, to maintain the participant's dignity as well as avoid confusion or frustration, for example by giving appropriate support for adjusting the settings on a smartphone or tablet according to the primary end user's needs and abilities. If it becomes clear that the primary or secondary user is stressed or frustrated by their participation (for example by the questions while the interview or by not being able to handle the my-AHA device), the researcher must (after discussing this with the primary and secondary end user) terminate the participation.

## 8.5 Reliability of my-AHA system

The functional capability of the my-AHA service must be tested several times before starting the trials, so that participants use a reliable and stable system. While the trials are going on, the secondary end user must have the chance to check important technical data (e.g., battery life, screen on/off, connection to the power net, and connection to the system/Wi-Fi) via the internet, to avoid confusion caused by a device that is not working properly.

 

There must be a technical support and clear procedure for every country so that any problems are solved as quickly as possible.

## 8.6 Freedom from harm

Care must be taken to ensure that participants' property is not damaged as a consequence of them taking part in the project (installation of devices, etc.).

Advice to researchers and carers must also be provided to ensure the personal safety of the primary my-AHA user. This is important in the context of the content production.

Example:

Daily activities that may be dangerous or harmful to the primary user must be avoided.

# 9 Applying codes, regulations and guidelines to specific areas of the my-AHA system development activity

## 9.1 Data

Distinction shall be drawn between personal and research data. Personal data is any data by which possession of could identify an individual. Research data are the metrics collected as part of the research and solely by which an individual cannot be identified. Personal data may also be research data. All processing of personal data (which includes the obtaining and storage of data) must comply with the terms of the Data Protection Act 1998 (http://www.legislation.gov.uk/ukpga/1998/29/contents). It is recommended that researchers familiarise themselves with published guidance which interprets the application of the Act and any other relevant legislation that is pertinent to specific fields of research.

## 9.2 Data protection and security

The my-AHA system will need to be designed to collect and store "only relevant information" (EU Directives). It has to be ensured that only a limited and authorised circle of people has access to the personal data. It has to be transparent for the users, "what data are collected, where they are stored, and for what purposes they are used" (ibid.). Simultaneously users have to give, "permission to the collection of data, storing and redirecting" (ibid.). See Section 4 on page 5 for details of the EU Data Protection Directive.

Personal information must be secured properly. This covers user names and passwords, management of personal user profiles etc. The technical solution must also secure that it will not be possible to access personal user information through the social network of the my-AHA system.

## 9.3 Autonomy and beneficence

Autonomy demands good knowledge of the technology and how to control it. In the case of the application design it has to be ensured that, "the control using the system stays with the user, even if the system is invisible or continuously on"; the user has to have "tools to start, stop and configure applications", "gets clear feedback on applications and functions that are on" and "gets sufficient feedback on what is happening in the application" (Ikonen et al. 2008).

Autonomy and beneficence for the primary end-user are driving forces behind the my-AHA initiative. In a homecare situation, application of such assumptions and principles is not always straightforward, given, e.g., conflicts of interest between different parties (the person in need of care, the primary carer, the family etc.). There is a need to evaluate what "feels right or wrong". To address these aspects it is reasonable to suggest that technology deployment departs from a relationships analysis between the person in need of care, the formal and informal carers, paid staff, the family etc. Trust and comfort are key issues. Possible conflicts or stressful relations between primary and secondary end-users (e.g. family requiring monitoring/tracking, and the primary end-user refusing to be monitored or "wired") will clearly not offer a fruitful or ethically acceptable point of departure for any test, trial or pilot. Distributive ethics from the perspectives of justice, equality of access, choice) will be applied in the my-AHA project. This concerns the overall balance between technology-driven, business-driven and socially-driven research. Transparency of interests and orientations, given the strong industry/business involvement in this research, is crucial.

### 9.3.1 Useful questions for developers to answer and revisit during the project

1. Who are the real beneficiaries of the my-AHA devices? (end-user, the carer and/or the care organisation, or other?)
2. Whose definition of benefit is being applied?

 

3. What are the costs and benefits (physical, emotional, psychological, ethical, and/or financial) of using the my-AHA devices, and to whom do they apply?

For example:

a) Does it support the person's autonomy or simply reduce risk?

b) Can a balance be struck, ensuring the wellbeing of both/all parties?

c) Is an individualised risk and wellbeing assessment is needed?

## 9.4 Integrity and dignity

Technologies should not be a substitute for real social contact and, "level of intervention should be restricted to what is really necessary for the situation" (Empirica and WRC 2009). For dignity, the project must support self-activity and self-fulfilment, social contact, positive self-image, and one's own realisation of security and satisfaction.

## 9.5 Reliability

Technology must be reliable, dependable and usable not only for the person receiving care, but also for caretakers. On the other hand the user should be in a position to turn off the system when they feel bothered by it. The my-AHA device has to take care for such a situation by making sure that the end user cannot be harmed (Empirica and WRC 2009: 38). Safety is a sensitive matter in the intersection of autonomy and reliability.

## 9.6 Role of technology in society

Applications and assistive technologies should be developed for increasing the quality of life, reducing harm and producing benefits for its user.

The my-AHA device aims to increase quality of life through supporting the independence and autonomy of the end user, and through reducing burden on carers. The system could potentially reduce harm for end users through its provision of clear guidance on how to carry out tasks. However, particular care needs to be taken to identify potential risks for end users and carers and to take all reasonable steps to reduce the likelihood of either party coming to any harm.

## 9.7 Equality of access

The application should be designed for every user group; respectively, "no user group should be ignored without strong reasoning" (ibid.: 9). However, it may be required to make a difference between people with minor cognitive impairments and people with dementia, or people with other disabilities. Therefore it should be possible to offer different services for specific needs of different groups.

"The lack of adequate infrastructure in certain regions and the absence of computer literacy in certain sections of the population" (Empirica and WRC: 12) have to be minded. Therefore, minimal requirements for implementation and an "age-friendly or layperson-friendly design" is an important goal. It has to be ensured that people are able to use these technologies and knowing about, "purposes, functions and what use they may get from them" (ibid.: 14).

The design of the my-AHA device will be based on user requirements that have been determined from the user involvement activities, as well as from well-regarded accessibility guidelines such as Web Content Accessibility Guidelines WCAG 2.04) to user interaction such as:

- Adopt familiar user interface concepts; based UI/UX designs on established user patterns.

- Ensure clarity of presentation and aesthetics of IADL multi-media material in all modalities (pictures, video clips, sound, etc.).
- Place emphasis on the ease of use of interactive elements.
- Reduce speed of spoken messages and other sound-feedback.
- Avoid childishness, special and overly decorative design elements of any information.
- Make sure that icons and other graphics on the primary end-user's IADL tablet are logical and self-explanatory to this age group.

Special attention needs to be given to the principles for Universal Design (UD) and Design for All. UD-principles such flexibility in use, simple and intuitive use, perceivable information, tolerance for error, low physical effort, size and space for approach and use need to be integrated with the my-AHA project's working practices.

## 9.8 Gender issues

Articles 2 and 3 in the Treaty of the European Union declare the European Policy of equal opportunities between women and men. The gender mainstreaming strategy adopted by the Commission contributes to promote the gender equality. In order to guarantee relationship of equality the following action item are of importance

- Research must address women's needs, as much as men's needs equally,
- Balanced membership of woman/men for both as scientists/technologist and as users for the field studies,
- Research must be carried out to contribute to an enhanced understanding of gender issues.
- Ensuring gender equality means giving equal consideration to the life patterns, needs and interests of both women and men. Gender mainstreaming thus includes also changing the working culture. The my-AHA proposal will design, develop and take forward a range of activities ensuring that the benefits of the platform fulfill the needs of both women and men.
- In the my-AHA project gender equality is to be understood along the following aspects
- In order to ensure a gender sensitive development of the integrated care portfolio, gender related research questions will be defined in early stage of the project.
- In the project women will be involved in products/services specification and development phases with same importance as men. This will include women's attendance in the whole design and evaluation process, starting by requirements till the reflection of design mockups, prototypes and products. Feedback for redesign from men and woman will be considered the same way.
- The project will identify and eliminate gender-related access barriers to technologies and applications.
- The different views on technology will be considered as advantages. The design of the applications will provide a good user experience (UX) to stimulate both, men and woman's needs.
- All consortium members commit to the gender strategy

## 9.9 Data sharing

The principles of data sharing are widely recognised and underpin many international activities. A report on "Principles and Guidelines for Access to Research Data from Public Funding.." by the Organisation for Economic Co-operation and Development (OECD, www.oecd.org) which represents the governments of its 30 member countries (including the UK) highlights the following principles:
• Publicly-funded research data are a public good, produced in the public interest
• Publicly-funded research data should be openly available to the maximum extent possible.

The report concludes that widespread data sharing will enable researchers, empower citizens and convey tremendous scientific, economic, and social benefits. The University subscribes to these data-sharing principles and aims to see the widespread ethical use of high quality data to advance research endeavor. We are committed to creating a scientific culture in which data sharing is embedded to facilitate more rapid

 

scientific and social advances. Researchers will be responsible for liaison with discipline specific external data repositories to ensure that publically funded research data should be openly available. Where no such resource exists applicants may consider sharing data via other third party mechanisms such as journal websites and / or open access repositories, many of which are now able to capture and share data underpinning publications.

# 10 Recruiting and working conditions for researchers

Recruiting rules are described in section 4 of the CA, article 32. In the following article 33 is described the obligation to aim for gender equality and a gender balance.

# 11 Publications

Authorship of an academic publication confers credit and credibility on the individual and the university and has important academic, professional and financial implications. Authorship carries with it responsibility for the content and accuracy of the published work.

## 11.1 Eligibility of authors

Collaboration and shared authorship are common in most academic disciplines. The general rules for assigning authorship vary between institutions, disciplines, journals, academic societies and the major academic publishing houses but are broadly in agreement. All authors should be aware of these guidelines as their incorrect application can lead to tensions and mistrust within a research group, delays in the submission of papers and, very occasionally, charges of academic misconduct and resulting sanctions.

## 11.2 Qualification for Authorship

Authorship should be limited to those who have made **significant contributions in a combination of**:

(i) conception and design of the project;
(ii) execution and/or acquisition of data
(iii) analysis and interpretation of research data;
(iv) drafting significant parts of the work or critically revising it so as to contribute to the interpretation of the work.

**A person who qualifies as an author according to the above criteria must not be included or excluded as an author without their permission**. This should be in writing, and include a brief description of their contribution to the work.

The right to authorship is not tied to position or profession, and does not depend on whether the contribution was paid for or voluntary. It is not enough to have provided materials or routine technical support, or to have made the measurements upon which the publication is based. ***Substantial intellectual involvement is required.*** Acquisition of the research funding, giving feedback on early manuscripts drafts, and general supervision or co-supervision of the research do not, on their own, constitute legitimate authorship. Furthermore, institutional position is insufficient for attributing authorship and senior academics must be careful not to apply pressure to their junior colleagues to be included as an author unless the agreed conditions are satisfied.

All authors listed on the manuscript must have approved its submission and publication, are responsible for drafting, writing, and revising the article, and checking and confirming the article prior to submission. All authors accept responsibility and accountability for all content and, if the article is found to be unsafe, in error, or in some way fraudulent, the responsibility is shared by all named co-authors. All authors agree that the corresponding author is empowered to act on their behalf with respect to communication with the journal's editorial office on submission and during the peer review process, including the coordination of revisions and preparation of a final version of the article.

## 11.3 Honorary Authorship

Authorship is sometimes granted to those who have played no significant role in the work but this is not only dishonest but also has the effect of reducing the credibility of the paper and those who did the work. All co-authors must be able to understand and support a paper's major findings and conclusions.

## 11.4 Ghost authors

A ghost author is someone who makes a contribution to the research and/or the writing of the paper, but is *not* listed as an author. Statisticians, those providing analytical support, technical writers, proof readers and editors may be ghost authors. It is legitimate for these contributors to be named in the Acknowledgement section. However, their exclusion from the author list must be agreed by all parties.

Genuine contributors and would-be authors should not be excluded because they 'have left the institute'.

## 11.5 First/Corresponding Authors

The principal author is the individual who has the primary responsibility for communication with the journal during the manuscript submission, review, revision and publication process. The principal author's duties are to:

(i) decide who is named as an author and in what order authors are listed;
(ii) decide whose contribution is acknowledged;
(iii) resolve claims or challenges relating to authorship; and
(iv) discuss any proposed changes to authorship and order of authors at the proof stage.

The principal author should be available throughout the submission and review process to respond to editorial queries in a timely way, and should be available after publication to respond to critiques of the work, correspond with readership inquiries, and to cooperate with any requests from the journal for data or additional information should questions arise with regard to the veracity of the paper. Sometimes, if the principal author moves to other employment and no longer has an academic or research involvement, the senior author may be identified as the corresponding author.

## 11.6 Open access

The Open Access policy applies to all members of staff employed in the my-AHA project. It requires that:

- All research papers (including journal articles, conference proceedings, book chapters and similar material), where copyright allows, should be made available in an open access form upon publication;
- All research papers (either in the form of the author's final manuscript or the formally-published version), where copyright allows, should be deposited in the my-AHA repository on the website upon publication or as soon as possible thereafter;
- Where available, researchers should take advantage of opportunities to publish their work in an open access form offered by journal publishers.

 

# 12 Intellectual property

IP is defined as: "The products of creative effort". It includes, but is not limited to, the results of research in the form of data, inventions, notes, records, books, papers, designs, art work, music, software, business methods, schemes for processing and assessing information and mathematical formulae. IP Rights are the legal rights that protect IP from inappropriate use or exploitation by others. The forms of IPR consist of the following:

- Patents
- Copyright
- Database rights (form of copyright)
- Registered and unregistered design rights
- Registered and unregistered trade marks

IP generated by members of the my-AHA consortium will be dealt by the committees of the Consortium, in agreement with the EC and national laws, and in agreement with the internal rules of the Universities and companies to which the members belong. Transfer of ownership to third parties, identified in the Consortium Agreement Annex 3, is ruled by the Consortium Agreement section 9.

Issues on IP are mostly dealt in the Grant Agreement Article 30 and in the Consortium Agreement in the section 9 “Ownership of Background and Results”.

# 13 Conflicts of interest

If members of the consortium have any third party pecuniary or non-pecuniary interests, or involvement in other projects which may give rise to conflicts of interest in carrying out their duties in the my-AHA project, they should report them to their Coordinator and PMB, where it will discussed.

# 14 Responsibilities and procedures

All colleagues in the my-AHA consortium are required to read and comply with the content of this document.

The nominated my-AHA Test Officers in each country are responsible supervising the fulfilment of this code of conduct throughout the project.

Any ethical questions arising during the my-AHA project need to be referred to the nominated Ethics Advisory Board who has a coordinating role for this. It is possible that ethical concerns or dilemmas will need to be referred to ethics committees if ethics approval had been required in a particular country.

# References

[1] http://www.my-AHA.eu

[2] http://www.respectproject.org/code

[3] Code of conduct and research ethics, University of Nottingham

[4] ESF European Code of Conduct for Research Integrity

[5] https://www.researchgate.net/publication/259573911 Code of conduct for FP7 researchers on medical and biometric data privacy. Towards Responsible Research and Innovation in the Information and Communication Technologies and Security Technologies Fields

[6] 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) (Text with EEA relevance) (http://ec.europa.eu/justice/data-protection/)

[7] T.L. Beauchamp and J.F. Childress, Principles of Medical Bioethics, Oxford University Press (2002)

[8] Mental capacity act (http://www.legislation.gov.uk/ukpga/2005/9/contents)

[9] Ikonen et al., Ethical Guidelines for Mobile-Centric Ambient Intelligence (http://www.fp6-minami.org/fileadmin/user/pdf/WS/MINAmI_EthicalGuidelinesforAmI.pdf)

[10] Empirica and Work Research Centre (2009): ICT & Ageing: European Study on Users, Markets and Technologies. Compilation Report on Ethical Issues. Available at: http://www.ict-ageing.eu/ict-ageing-website/wp-content/uploads/2008/11/d11_ethics_compilation_rep_with_exec_sum.pdf

[11] *Hit enter here to create a further reference*

 

# Annex A Ethical and legal issues from the my-AHA proposal

Assistive technologies for independent living at home offer a lot of promise. However, attention needs to be given to a number of ethical concerns. Some are directly related to the characteristics of the technology, some to issues of preferences and choices. Ethical aspects in the project concern the fieldwork and involvement of end-users (starting from analyses of end-user needs, requirements and personal preferences, and proceeding to user tests and field trials), the management of research data, and the use of the technology itself, as described below.

The consortium has solid experience from working with older persons, and ethical issues that may arise. The user organisations work mainly with primary end-users (older persons). Several of the consortium partners have expertise in involving people with memory impairments and intellectual disabilities in their research and development work. The consortium's knowledge of the target group is also based on a literature review carried out, and input form focus groups on the new products with experts and secondary end-users.

First of all, we will ensure that all fieldworkers have or receive appropriate training and knowledge concerning ethical issues of undertaking research with end-users, including user test, field trials or pilots, will be carried out in compliance with established ethical and privacy regulations. In particular, the test/trial/pilot planning will consider the ethical guidelines for research in science and technology as established in each country conducting user tests and field trials, guides concerning reporting and careful handling of personal data, and regulations of use of personal data within research projects. Ethical guidelines for field work will be developed in WP7. In particular, these will include procedures to manage issues that might arise relating to possible discomfort or even misuse of the intended products or technologies introduced to the primary end-user. All involved parties will sign a non-disclosure agreement.

Any handling of personal data will comply with the respective national data acts and the following legal entities:

- Charter on the fundamental rights of the European Union (2000/C364/01).
- The 95/46/EC Directive on the processing of personal data and the following Regulation 2016/679.
- The RESPECT Code of Practice15 as reference material for development of my-AHAs ethical guidelines.

In case challenging ethical issues arise during the project, national ethical committees will be consulted System logs that enable end-user identification will be made anonymous. In all cases of fieldwork, the dignity of all involved end-users will be treated appropriately. By dignity we mean the personal experience of confidentiality and personal comfort when using or being monitored by ICTs, including sensors, alarms or the like. The primary end-user of the my-AHA project uses non-stigmatising devices, such as generally available tablet PCs or smartphones. This strategy is adopted by the project in order to stimulate the use of the device by older persons who wish to appear as users of modern technologies, and bring this achieved capability into the later use situations in which more support is needed, but where there still is a need not to exhibit use of "elderly-technology". Procedures, information material and schemas for informed consent will be developed for user tests, trials and pilots. In particular, formal and informal carers will be contacted in each individual case. Adequate and appropriate information material about the project and its goals and methods will be prepared for informing both primary and secondary end-users. User tests and field trials will reveal the most important parameters with respect to dignity. These test results will be taken into account very precisely in order to produce an acceptable design for users with privacy concerns.

Consequence ethics ("insight from consequences") is an important approach in technology deployment for elderly users. (…) There is a need to evaluate what "feels right or wrong". To address these aspects it is reasonable to suggest that technology deployment departs from a relationships analysis between the person in need of care, the formal and informal carers, paid staff, the family etc. Trust and comfort are key issues. Possible conflicts or stressful relations between primary and secondary end-users (e.g. family requiring monitoring/tracking, and the primary end-user refusing to be monitored or "wired") will clearly not offer a fruitful or ethically acceptable point of departure for any test, trial or pilot. Distributive ethics from the perspectives of justice, equality of access, choice) will be applied in the my-AHA project. This concerns the overall balance between technology-driven, business-driven and socially-driven research. Transparency of interests and orientations, given the strong industry/business involvement in this research, is crucial.

All ethical matters will be treated and managed in WP7.