PROJECT

Coach assistant via projected and tangible interface

GRANT AGREEMENT

Nr. 769830

D1.2. – First Version of Ethics and Safety Manual

SUBMISSION DUE DATE

Month 6, 31st May 2018

ACTUAL SUBMISSION DATE

Month 6, 31st May 2018

DELIVERABLE VERSION

#3.0

This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 769830

DELIVERABLE TITLE	< First Version of Ethics and Safety Manual >
DELIVERABLE No.	D1.2
Deliverable Version	#3.0
Deliverable Filename	D1.2_Ethics and Safety Manual_v3.0.docx
Nature Of Deliverable	R = Report
Dissemination Level	
Number Of Pages	20
Work Package	WP1 - <Management>
Partner Responsible	MU
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PROJECT FULL TITLE	Coach assistant via projected and tangible interface
Type Of Action	Research & Innovation Action (RIA)
Topic	H2020-SC1-PM-15-2017: Personalised coaching for well-being and care of people as they age
Start Of Project	1 December 2017
Duration	36 months
Project URL	www.captain-eu.org

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1 INTRODUCTION

1.1 BACKGROUND AND MAIN ETHICAL PRINCIPLES

The objective of CAPTAIN is to develop and test a “transparent” technology designed to turn the home of the older adult into a ubiquitous assistant to offset their memory impairments and/or empower to make them independently during ADL. To accomplish this aim, CAPTAIN will exploit “Projected augmented reality” and 3D sensing technologies. In carrying out these objectives, it will be necessary to involve all the supply chain from the end-users to healthcare professionals.

The CAPTAIN innovation technologies will address problems experienced by persons living with early stages of dementia, loss of memory or in a new phase of life where they are ageing. The acceptance and adoption of healthcare and assistive technologies depends on a close collaboration between end users and technologists from the early phases of the deployment of CAPTAIN.

It is within this framework that the ethical challenges relating to user involvement in the CAPTAIN project need to be considered by the consortium. Ethical conduct is a cornerstone and main characteristic in modern scientific research. Because scientific research often consults with human subjects directly and/ or indirectly, it is essential that special attention is paid to ethical scientific research. Within the H2020 research framework, we need to define three major directions of ethics in scientific and industrial research:

- An academic discipline. Ethics is the critical study of the norms that guide our actions.
- Practical skills. Ethics is the practical art of knowing how to apply moral principles in concrete situations.
- Value systems. Ethics deals with the core values that guide a person or an organisation on the way to its shared vision.

The European Commission defines the principles of European research ethics through the following points:

- **Respect for human dignity:** Respect for persons requires that subjects, to the degree that they are capable, are given the opportunity to choose what shall or shall not happen to them. This opportunity is provided when adequate standards for informed consent are satisfied, and these standards include:
    - Information: The extent and nature of information should be such that persons, knowing that the procedure is neither necessary for their care nor perhaps fully understood, can decide whether they wish to participate in the furthering of knowledge. In other words, the information should be sufficient so that a "reasonable volunteer" can decide whether to participate.
    - Comprehension: Information should be provided to potential subjects in such a way that they could understand what is being conveyed. Because the subject's ability to understand is a function of intelligence, rationality, maturity and language, it is necessary to adapt the presentation of the information to the subject's capacities. In CAPTAIN,

investigators will be responsible for writing the plain language statements in a way that participants can comprehend the information.
    - Voluntariness: An agreement to participate in research constitutes a valid consent only if voluntarily given. While research participation is rarely coerced, undue influence can be part of the consent process when there is inequitable social pressure or there are inappropriate rewards to participate.

- **Privacy:** It involves respecting an individual's right to privacy, the right to control access to one's self and information, and protecting the confidentiality of private, identifiable information about individuals. The CAPTAIN consortium will ensure that the subject's right of privacy is not violated and the confidentiality of information is protected. It will be clearly specified which data are collected, how they are processed, and who can access them. Privacy problems exist wherever uniquely identifiable data relating to a person or persons are collected and stored, in digital form or otherwise. Improper or non-existent disclosure control can be the root cause for privacy issues. The challenge in data privacy is to share data while protecting personal identity. The most common sources of data that are affected by data privacy issues are:
    - Health information
    - Criminal justice information
    - Financial information
    - Genetic information
    - Location information
    - Cultural information
    - Religious and political convictions
    - Ethnicity information

- **Beneficence:** The principle of beneficence includes the obligation of researchers to strive to do no harm and to maximize benefits and minimize harms. For the fulfilment of the ethical standards of this principle, a series of procedures should be kept in mind:

    - Systematic assessment of risk and benefits: There is need to determine that the risks are justified by the research's anticipated benefits. Risk does not mean harm, but it is the possibility of harm, and an analysis of the risks must take into account both the magnitude of the possible harm and the probability that the harm may occur. The research's anticipated benefits may be to the individual research subjects or they may be to others in the form of the advancement of scientific knowledge.

    - Minimization of risks: In addition to determining that the risks are reasonable in relation to the anticipated benefits, the principle of beneficence requires that the risks in the research are the minimum required to achieve the research objective. Where necessary, alternative, less risky procedures or modifications to the procedures need to be explored that reduce the magnitude or probability of the possible harm to subjects. This links with the principle of Non Maleficence (which involves causing no harm, or the least harm that is possible in comparison to the benefits obtained).

- **Justice:** The principle of justice requires that the selection of subjects is equitable. The principle of justice requires a fair sharing of the burdens and benefits of research and that groups are not exploited because of their circumstances. The selection of subjects must be based on the research's scientific needs, not on convenience in recruitment. Researchers should be able to scientifically justify the inclusion or exclusion of subjects.

- **Proportionality:** The level of information collection must be limited to what it is strictly necessary. If the same information can be collected by less invasive procedures, and in less time, the researchers must follow procedures that ensure that the information is collected in a way that collects the minimum amount of data and minimizes the inconveniences to the participant.

- **Utility:** Information must not be collected unless the goal to do it is clearly specified. It directly links to proportionality, respect and privacy. The technologies involved in the CAPTAIN project will collect the minimum amount of information that is necessary for the goals of the project, and this will be clearly specified in each research stage.

- **Autonomy:** It implies that each participant may decide what is better for them and that must be respected. The individual may experience autonomy each time they perceive that their behaviour is congruent and self-initiated. Participants in CAPTAIN need to be in control of the decision-making in terms of their desire to participate, stay and leave the project at any time they consider.

- **Integrity:** This implies that physical and psychological conditions of the participants must be respected and that nobody can violate them without an explicit and informed consent. In CAPTAIN, no physical harm is predicted and psychological factors such as anxiety may be involved if the participants (especially in real home settings) have a concern about their privacy. These issues will be properly addressed and documented in the informed consent forms for each of the different research stages.

- **Transparency:** The goals and purpose of data collection must be clearly explained to the participants, and, where necessary, to relatives. It links directly with the nature and features of the informed consent form.

In terms of Data Protection, all the CAPTAIN activities will be compliant with the General Data Protection Regulation (GDPR) that enters into place on the 25th May, 2018. Before that, Directive 95/46/EC is the reference text, at European level, on the protection of personal data. It applies to data processed by automated means (e.g. a computer database of customers) and data contained in or intended to be part of non-automated filing systems (traditional paper files). It sets up a regulatory framework that seeks to strike a balance between a high level of protection for the privacy of individuals and the free movement of personal data within the European Union (EU). To do so, the Directive sets strict limits on the collection and use of personal data and demands that each Member State set up an independent national body responsible for the protection of these data. This directive defines personal data as "all information on an identified or identifiable person", considering an identifiable person as anyone whose identity might be determined, directly or indirectly, in particular by means of an identification number or one or several

specific elements, characteristics of his physical, physiological, mental, economic, cultural or social identity and attributes special protection to health data.

The **Charter of Fundamental Rights of the European Union (2000/C 364/01)** aims to make more visible to the Union's citizens the fundamental rights that they already enjoy at the European level. It brings together those rights that are scattered throughout many different sources. It includes, without adding new legislation or jurisprudence, the protection of personal data, as well as rights in the field of bio-ethics, required by advances in information technologies and genetic engineering. Finally, by expressing rights that were at times buried in the abundant jurisprudence of the Court of Justice of the European Communities, it responds to legitimate demands for transparency and impartiality in the functioning of Community administration.

The European Charter of Fundamental Rights states:

Art 3: Right to the integrity of the person

1. Everyone has the right to respect for his or her physical and mental integrity.
2. In the fields of medicine and biology, the following must be respected in particular.
3. The free and informed consent of the person concerned, according to the according to the procedures laid down by law.
4. The prohibition of eugenic practices, in particular those aiming at the selection of persons.
5. The prohibition on making the human body and its parts as such a source of financial gain.
6. The prohibition of the reproductive cloning of human beings.

Art. 8: Protection of personal data

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

Art. 13: Freedom of the arts and sciences

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

The European Directive on the protection of personal data contains a number of key principles that must be complied with. Anyone processing personal data must comply with the eight enforceable principles of good practice. They say that data must be:

1. Fairly and lawfully processed.
2. Processed for limited purposes.
3. Adequate, relevant and not excessive.
4. Accurate.
5. Not kept longer than necessary.
6. Processed in accordance with the data subject’s rights.
7. Secure.
8. Not transferred to countries without adequate protection.

With the new GDPR that will enter in place by the time this manual is submitted, the potential conflicts or disagreements between national legislations of countries and partners involved in the CAPTAIN project will no longer affect the development of the project, as this data protection will be regulated by this new regulation at a European level. The implications of the GDPR for CAPTAIN project are further detailed in the CAPTAIN Data Management Plan (deliverable D1.5).

1.2 SCOPE OF THIS MANUAL

The goal of this Manual is to provide CAPTAIN partners with clear guidelines about the type of procedures and principles they need to follow to guarantee an ethical and safe user involvement throughout all stages of the project. A description of different project stages will be presented, followed by procedures to monitor gender and equality issues, user involvement strategy, inclusion and exclusion criteria, and procedure for incidental findings. Finally, templates detailing the type of contents that need to be included in Consent Forms and Plain Language Statements (information sheets) will be described.

2 DATA PROTECTION PLAN FOR CAPTAIN PROJECT

2.1 MONITORING OF GENDER AND EQUALITY ISSUES

Throughout all stages of the research programme, the issue of gender and equal opportunity will remain to the fore. For all planned studies, efforts will be made to recruit approximately equal numbers of both males and females. The research team is clearly gender balanced and the consortium is aware of the importance and relevance of gender (and indeed a range of other demographic variables). As a result, gender issues will be considered carefully both when conducting the literature review and test evaluation and in terms of recruitment of study participants for all stages of the project. Ultimately, research in this area must always identify and recognise potential gender differences in symptoms or indicators of MCI or dementia. If, as recruitment progresses, it becomes apparent that relatively small numbers of either males or females volunteer for our studies, relative to the other group, we will seek to revise our recruitment strategies.

2.2 DATA COLLECTION STAGES

It is relevant to distinguish between different stages that will require user involvement:

- **Initial consultation phase:** this requires the recruitment of target users for the administration of surveys or discussion of the project idea and how they envision the applicability of the CAPTAIN platform in their daily lives. It is a phase in which there is no need to collect any data from the users, except their opinion on the concept and technology of CAPTAIN, and to check whether they consider it a usable and acceptable technology as it is initially conceptualized. The only relevant personal information that would be required at this stage is basic sociodemographic data such as age and gender, for the purpose of providing a general overview of the focus groups. The level of sensitivity of shared information is quite low so the consent form will just inform participants about the topic for discussion and ask for their agreement to participate. It is not foreseen that there will be a need to seek ethical approval to conduct surveys and discussion on technology

acceptance topics that do not involve disclosure of personal information. Anyway, involved living labs could consult their local competent Ethical board/committee for further advice on this subject, if needed.

- **Data collection for the production of experimental datasets:** This stage aims to train the CAPTAIN components to detect the presence and activity of target users, and thus be able to prompt them and provide support in the way it is envisioned. For this goal, involvement of users does not necessarily require only the involvement of target older users; any adult volunteer can be involved for the purposes of training the system. At this point, it is likely that the type of information collected by the system will include sensitive personal data if it includes face tracking, voice recognition, etc. At this stage, the participants would be required to consent for participation and for having the data stored and accessed by project partners based on the procedures described in Deliverable 1.5.

- **Data collection in Living Labs:** Living labs will follow a coordinated, synchronized procedure of stakeholders involvement and data collection, in a way that all sprints with stakeholders start and finish on the same dates and in the same way according to the Study plan (deliverable 7.1). The precise methodology will be described in the methodology for the pilot trials in the living labs (deliverable 7.3). In terms of data collection, the consent form will specifically include:

    - (1) agreement to participate,
    - (2) a list of the different kinds of data that are going/expected to be collected across all the sprints including the modality of data treatment. Stakeholders will be informed of all of the different potential types of data that may be collected from the beginning, at least a general overview of the type of data (knowing that using an agile methodology may make difficult to be completely specific from the first sprint) even if initial sprints do not require collection of all “those” data. This is the best way to ensure that participants are fully aware of the nature and extension of data collection that is expected across the whole pilot trials in the living labs.
    - (3) Consent for data to be available in open data sets: participants will be presented with a checklist of data and they will need to check and provide permission for each kind of data (e.g. physical data, video data, audio data…) to be made openly available.

- **Data collection in Real Homes:** This is the most sensitive stage in terms of the private environment in which the data collection is going to take place, and also the environment in which there is an absolute need to guarantee that principles of privacy, utility, and proportionality, among others, are clearly observed and fulfilled. Users will be asked to agree to participate and adhere to the study protocol and a specific consent form detailing the level of participation, types and amount of data collection, resources to be used for that data collection (e.g. questionnaires, structured interviews, etc.), procedures related to the participation in the study, time of engagement, and agreement on sharing specific type of data (and how each specific type of data will be shared) will be enhanced.

2.3 USER INVOLVEMENT STRATEGY, INCLUSION AND EXCLUSION CRITERIA

Depending on the specific stage of the project, end users and other stakeholders (e.g. informal and formal carers) will contribute to the discussion on user needs as part of requirements gathering and evaluation in a continuous process. The stakeholder network engaged for the co-creation and testing activities in the living labs will be detailed in deliverable D2.4 (Final version of user requirements analysis) and D7.3 (Pilot trials in living labs methodology) and should involve both primary users (older adults) and secondary users (formal and informal caregivers) and other profiles (health managers, health technology providers, seniors association representatives, technology support staff, etc.). The methods for eliciting user needs include face-to-face interviews, focus group discussions, and questionnaire-based surveys; data collection may use video and audio recordings. Additional methods could be defined according to the methodology for the pilot trials in the living labs (deliverable 7.3). The data thus collected may include personally identifiable information (PII) as well as some health information (e.g. regarding mobility or diagnosed condition). Such information will always be anonymised and kept in secure locations. As the deployment process evolves, CAPTAIN will be evaluated and feedback will be gathered again through interviews and surveys. All activities involving users or their carers will take place only after ethical approval has been granted from the appropriate regional/national ethics bodies.

Participants recruited for the study in Real Homes will be community dwelling older adults who are still able to provide informed consent. Strict inclusion and exclusion criteria will be adopted in order to ensure that only adults who are able to consent are recruited and these inclusion/exclusion criteria will be detailed in all study information and recruitment sheets.

Inclusion criteria will comprise all people older than 60 years old, experiencing, at most, MCI, mild dementia or some form of physical impairment. Participants must also be able to understand the objective of the study and to provide written and signed informed consent (as a result of a fully informed understanding of the implications of participation). Exclusion criteria will prevent participation from those with sensory difficulties that make them unable to interact with the CAPTAIN system, those with a history of learning disability and those with current or previous psychiatric diagnoses (e.g. schizophrenia, bipolar disorder, etc.), or those in moderate stages of dementia or other conditions that make them unable to provide consent to participate in the study.

2.4 PROCEDURE FOR INCIDENTAL FINDINGS

Given the nature of the study, it is possible that cognitive difficulty reflecting MCI and / or dementia may be detected in otherwise healthy adults. It is also possible that the full extent of physical, cognitive or other difficulties detected in those participating in the study might be greater than that previously detected. Where deficits are detected that might be a cause of concern, participants will be advised to consider consulting with their GP for further evaluation. As part of the informed consent process, participants will be informed that should any issues of concern arise during or as a result of participation in the study, a brief report will be issued to their relevant doctor(s), whose names will have been provided in advance of testing and who will already be aware that their patient intended to participate.

All the participants will be entitled to request, in writing, feedback related to their performance and this feedback will be provided in the form of a short report prepared under the supervision of the project supervisor in each setting. As will be detailed clearly the study information sheet and informed consent form, the report is delivered within a research framework and does not constitute a report prepared for

diagnostic purposes. Should they have any concern about the results, or, as stated above, should any incidental finding regarding their physical or cognitive status arise during the evaluation process, participants will be advised to consult with their GP for further evaluation.

Another potential issue could be related to the safe installation of devices and technologies in the living labs. The consortium needs to ensure and certify that the use of the technology involved in CAPTAIN is safe for the individual, that no harm of any kind are expected due to the use of the technology involved in the project and a sort of civil responsibility insurance agreements should be established between the CAPTAIN consortium and the participants, in order to guarantee that both the integrity of the equipment and the participants are considered, covered and guaranteed. More specifically, an insurance covering the study sponsor and Principal Investigator in each pilot site against damages on participants will be hired, and potential adverse events related to the use of technology will be constantly monitored and reported when necessary.

In order to guarantee the participant's safety, he/she will be informed that if, at any time, the principal investigator determines it is not in the best interest of the participant to continue in the study (e.g. in case an increased risk), the person will be excluded from the study.

In case of an incidental finding that requires further assessment, the partner that detects the need to communicate this issue as a potential conflict for the ethical integrity of the project will raise the issue to the internal Ethical Board in CAPTAIN (composed by at least 1 member of each partner involved in the consortium). When the issue is minor (differences on how to process or share a particular kind of data between partners from different countries) and can be solved within the consortium, corrective measures will be adopted. When the potential ethical issue (e.g. a confidentiality breach) implies decision making and expertise beyond the scope of the CAPTAIN consortium, the project team will seek further assistance in external ethical review boards.

2.5 DOCUMENTATION FOR PARTICIPANTS

2.5.1 INFORMATION SHEET: CALL FOR VOLUNTEERS

This document will include a series of features that will be common for all partners involving end users. Below, a template for the recruitment of participants, that can be adapted by each partner, is provided.

Recruitment Advertisement

Call for Volunteers

Healthy volunteers needed to [DESCRIBE THE PURPOSE OF THIS STAGE OF THE PROJECT]

Study Background: Volunteers, age 60 years and older, are needed to take part in a study that seeks to [DESCRIBE THE GOAL OF THIS PART OF THE STUDY].

This research forms part of a larger research project that is designed to [DESCRIBED THE GENERAL GOAL OF THE PROJECT AND ITS RELEVANCE]. Thus, we are seeking volunteers with [DETAIL INCLUSION/EXCLUSION CRITERIA].

Who is involved? We are a team of researchers from [EACH PARTNER'S CONTACT PERSONS AND AFFILIATIONS] and the research project is funded by the European Commission.

What will the study involve? If you volunteer to take part in this study, you will be asked to [DESCRIBE WHAT THE PARTICIPANT WILL DO, FOR HOW LONG, AND WHAT TIME OF INFORMATION WILL BE COLLECTED AT THIS STAGE, IN GENERAL TERMS]

Why is this study beneficial? The information you provide to us in this study will help us understand the way in which [DESCRIBE].

How can I take part? If you are interested in knowing more about this research study, or you think you would like to participate, please contact the principal investigator [NAME OF CONTACT PERSON, PHONE NUMBER]. Alternatively, you can contact us by email at [EMAIL ADDRESS]. We will then send you a detailed information sheet related to the study so that you can make a decision about whether or not to get involved.

***Please note**:*

1. *Only those who provide informed consent will be eligible to take part in the study. Informed consent to participation will be documented through asking you to sign a consent form.*
2. *Because of the nature of this study, which is conducted for research purposes only, you cannot receive a diagnosis about your general health status as a result of your participation in this study. However, should you have any concerns about your memory, you can request a copy of your test scores for the attention of your GP.*

If, for any reason, you have concerns about whether or not to take part in this study or if you have any concerns about your health status, you should consider consulting your GP for advice.

Ethical approval for this project has been obtained from [NAME OF THE ETHICAL COMMITTEE AND REFERENCE NUMBER GIVEN BY THE ETHICAL COMMITTEE TO THE PROJECT APPROVAL]

For the specific sprints in the Living Labs, it is expected that, followed by a general Plain Language Statement (see Section 2.5.2), different information sheets for each sprint will be provided, so that the participants can get updated information sheets for each specific sprint. In this way, participants in living lab pilot stages will receive updated information about the type of data that will be collected within each sprint (e.g. physical, audio, video data…), and they will exercise their right to accept or refuse to share those data in each of the sprints.

2.5.2 PLAIN LANGUAGE STATEMENT

The Plain Language Statement (PLS) is the explanation of the CAPTAIN project and participation in that project at a language level that the participants can understand, according to their cognitive, educational or cultural level, such that they can fully understand the project goals. It will detail what their participations implies, what they need to do, and potential benefits and risks. It will provide reassurance on confidentiality of the data, how data will be processed and treated, their rights as participants to voluntarily participate and withdraw, and who to contact in terms of doubts or concerns about the study or their involvement in the study.

Below, we present a template with the different sections that the PLS will comprise, that can be adapted to the language and terms required by each partner when approaching end users in their respective countries and research facilities.

Plain Language Statement: Healthy Older Adults

Title of Study: [TITLE OF THE PARTICULAR STAGE OF THE STUDY]

Principle Investigator: NAME, PHONE NUMBER AND EMAIL ADDRESS

Co-investigators: NAME, PHONE NUMBER AND EMAIL ADDRESS

Introduction: Thank you for expressing an interest in this research study. The research is funded by the European Commission and is being carried out by [CONTACT INVESTIGATOR(S), NAME(S) AND AFFILIATION(S)]. Before you decide whether or not to participate, please read the following information carefully. If you require further information, or would like to ask any questions, please contact the research team.

Background and aims of the study: Our goal is [DESCRIBE THE GOAL OF THIS PART OF THE STUDY]. To do that, we need to [DESCRIBE IN GENERAL TERMS WHAT IS REQUIRED FROM PARTICIPANTS AND WHAT THE PROJECT AIMS TO ACHIEVE DOING THAT].

Am I eligible to take part in the study? To take part in this study, you need to be [REFER TO INCLUSION AND EXCLUSION CRITERIA].

What does participation in the study involve? If you agree to take part in this study, you will be asked to [DESCRIBE THE REQUIRED INVOLVEMENT, NUMBER OF APPOINTMENTS, DURATION OF EACH SESSION].

Are there any risks associated with the study? As this study requires you to [DESCRIBE TASKS], it is possible that you may become anxious or concerned about [DESCRIBE WHY THIS MIGHT POTENTIALLY HAPPEN]. It is also possible that we may notice that your performance is poorer than might be expected for someone of your age and background. It is important to bear in mind that poor performance on any of the tasks can be due to a number of possible reasons and will not automatically mean the presence of a cognitive disorder or other health concern. If we have any reason to be concerned about your level of performance [REFER THE POSSIBILITY OF CONSULTING A HEALTHCARE PROFESSIONAL]. If you do not wish to avail of this appointment, we will advise you to speak directly with your GP so that further investigation might be arranged if deemed necessary or desirable. If at any stage during your participation, you feel concerned, you can withdraw without any consequences. In addition, you are advised to discuss any concerns you may have about this study or about any aspect of your [COGNITIVE FUNCTION/HEALTH/OTHER] with your GP.

Are there any Benefits (direct or indirect) to my involvement in the Research Study? Your participation in this study will help us to clarify [DESCRIBE OUR INTEREST IN THIS STAGE OF THE PROJECT, WHAT WE WILL ACHIEVE THANKS TO USERS' PARTICIPATION]. This may or may not benefit you directly, but will benefit other people in the future who [DESCRIBE WHO WILL BENEFIT]. You should note that this study is for research purposes only, and cannot be used for diagnostic purposes. However, if you are concerned about your health in any sense, you can request feedback about your performance.

How will the information I provide be protected? How will my identity be protected? If you agree to take part, all information collected will be kept strictly confidential within the limitations of the law. Your name and any other personally identifiable information will be stored separately from your test data and that identifiable information will only be accessible to the research team. Findings published from this study in reports and journal articles will not contain any personally identifiable information. If you request individual feedback about your performance, this will be provided by [NAME THE RESEARCHER WHO WILL DO THIS].

What will happen to the data? The data collected for this study will be summarised and will be presented in study reports. The data may also be used for anonymised publication in journals or reports. Information will be stored for a maximum of 10 years or deleted at any moment upon a request of withdrawal from participation. A one-page summary of the research will be available upon request following completion of the study. Although individual feedback will not be offered as a routine part of the research, as mentioned above, you may request feedback on your performance, if you have concerns about your functioning.

Involvement in the Research Study is voluntary and you have a right to withdraw: Participation in this study is completely voluntary and there will be no penalty for withdrawing from the study at any time.

What to do if there are concerns about the study: If you have any concern about this study and wish to contact an independent person, please contact [GIVE THE CONTACT OF THE ETHICAL COMMITTEE THAT SUPERVISES THE CAPTAIN PROJECT IN YOUR COUNTRY]. You may also contact the project leader, [NAME, PHONE AND EMAIL OF THE CONTACT INVESTIGATOR FOR THE PARTNER INVOLVED].

What should I do now? If you are interested in completing the study, you will be contacted by the research team to arrange a suitable time for assessment. When you come to meet with us, you will be given a copy of this to read again before being asked to provide your written informed consent.

To whom I can ask for more information? You can obtain more information on the project on the website www.captain-eu.org. For further details on the study you can contact [GIVE NAME, PHONE AND EMAIL OF THE LOCAL CONTACT INVESTIGATOR]

Ethical approval for this project has been obtained from the [[NAME OF THE ETHICAL COMMITTEE AND REFERENCE NUMBER GIVEN BY THE ETHICAL COMMITTEE TO THE PROJECT APPROVAL]

2.5.3 CONSENT FORMS

For each project stage, two differentiated consent form variants will be provided. First, consent forms for participation that will focus on getting the participant's approval to participate in the project stage for which he is required and that is described in the accompanying PLS. Second, participants will be given a detailed consent form for data sharing with the description of data that will be collected, how these data will be obtained, how these data will be protected, and a checklist of the different kinds of data to be gathered so that the participants may decide which type of data they want to share or not.

2.5.3.1 CONSENT FORM FOR PARTICIPATION

The participation consent form will follow a template like this, adapted to each involved partner's language and circumstances.

Title of Study:

Principle Investigator: Name, phone number and email address.

Co-investigators: Name, phone number and email address.

Background and aims of the study: A brief paragraph describing again the goals of this stage of the project.

Participant – please complete the following [tick Yes or No for each question]

Have you read the plain language statement?	□Yes	□ No
Do you understand the information provided?	□Yes	□ No
Have you had an opportunity to ask questions and discuss this study?	□Yes	□ No
Have you received satisfactory answers to all your questions?	□Yes	□ No

Participation is voluntary: I have read this consent form. I have had an opportunity to ask questions about the consent from and all the questions have been answered to my satisfaction. I freely and voluntarily agree to be part of this research study, which respects my legal and ethical rights. I am aware that I may withdraw at any time, without giving reason, without this decision affecting me in any way, and all my collected data will be destroyed and no longer used, except in the case that test data have already been part of a published research. I have received a copy of the information sheet.

Confidentiality of Information: I understand that my consent form, containing my name and any other potentially identifying information, will be stored separately from my test data. Therefore, my test scores and other data will only be identifiable to the research team, and all my data will be stored securely. Confidentiality is assured but I am aware that confidentiality of information provided can only be protected within the limitations of the law.

Potential concerns about cognitive function: I am aware that this study is for research purposes only and that it is not a comprehensive assessment of cognition. Therefore, I will not receive, nor could I receive, any form of diagnosis as a result of taking part in this study. I am aware of the possibility that my participation in this study could cause me to feel a little anxious or concerned about my health status. I am also aware that the research team might notice that my performance is poorer than might be expected for my age and background. I am aware that should the researchers have reason to be concerned about my performance, they will offer me an opportunity to meet with a healthcare professional for advice. Should I elect not to avail of this opportunity to meet, I will be advised to consult with my GP.

Consent

I have read and understood this form. My questions and concerns have been answered by the researchers and I have a copy of this form for my personal records. In providing my signature below, I consent to take part in this research study.

Signature

Participant's signature: _____

Name in Block Capitals:_____

Date: _____

Ethical approval for this project has been obtained from the [[NAME OF THE ETHICAL COMMITTEE AND REFERENCE NUMBER GIVEN BY THE ETHICAL COMMITTEE TO THE PROJECT APPROVAL]

2.5.3.2 CONSENT FORM FOR DATA SHARING

Due to the different kinds of data that will be collected and potentially shared within the CAPTAIN project and consortium, it has been agreed that provision of information to participants requires a differentiation between consent forms for participation and consent forms for data sharing. In the latter, it is expected to present as many details as possible about the following issues.

Title of the project.

Partner Name.

Investigator's name and contact information.

Which data are collected and treated, and reason and goal to do that

How data will be anonymized and used.

Modality of treatment of user data: reassurance on confidentiality of data

Right to rectify or withdraw data: includes all the contact information necessary to do it.

Description of the legislation: One page described the participants' rights with regards to data protection, collection, sharing, and withdrawal.

Final page with the statement of awareness on how the data will be used, and agreement for data sharing

By signing this document, I (name and surname) give consent for the treatment of my personal data and for their eventual transfer even out of the European Union for the purpose of research, within the limits and on the modalities indicated in the information provided together with the current document and in agreement with the European General Data Protection Regulation. The consultation of the type of personal data that I allow to share are only for the purpose of this research. The staff accessing my personal information will comply with all the existing regulations in terms of data protection and confidentiality [NAME OF THE RESEARCHER] has given me a copy of the information sheet on the treatment of personal data, and a dated, signed copy of the current document [PARTICIPANTS SIGNATURE AND DATE].

2.6 DOCUMENTATION FOR ETHICAL APPROVAL

Ethics approval must be sought and obtained prior to commencing participant recruitment at the project host organisation and at any other collaborating organisation involved in the data collection. Consent must be sought from the participants prior to any data collection. The application for ethics approval will contain:

1) a summary of the project
2) research methodology and protocols, including how participants will be selected (inclusion and exclusion criteria), any risks associated with the project and how they will be managed
3) plain language statement/ information sheet (adapted for each partner location)
4) consent for participation (adapted for each partner location)
5) consent for data sharing (adapted for each partner location)
6) data collection forms and questionnaires

If the study includes the use of experimental technology, this additional documentation has to be provided:
8) Description of the experimental technology and its components
9) Technology user manual with indication for use

As detailed in previous pages, consent forms will clearly state the purpose and benefits of the research, and any associated risks, discomforts and adverse side effects, if any, resulting from participating in the study. The form will provide also explanation of confidentiality concerning personal information and data, a contact person who can handle requests for withdrawal from study and any consequences that may result from withdrawing, and a contact person who can respond to questions about the research.

2.7 DATA STORAGE AND HANDLING PROCESSES

Full description of the data management procedures for the CAPTAIN project are available in the Data Management Plan (D1.5). However, items closely linked with ethical approval are summarised here. Within the project, we will ensure that participant identity is protected to the greatest extent possible. However, given the intention to provide feedback when requested by participants and the intention to provide summary data to GPs/doctors, when appropriate, it is necessary to hold codes linking participant ID with test results. Thus, it is not possible to design a completely anonymous study. In order to protect personal identity, all participants will be issued an ID code that will then be the sole identifier on all test record forms (paper and- pencil and electronic -in the case of computer based tests).). The matching sheet linking IDs to participant's name and other data such as doctor's name will be held securely in a locked filing cabinet held securely, and will be accessible only to the PI. All other data will be encoded, and de-identified, using the numerical codes.

Psychological data collected in paper and pencil format will be stored in hard copy format (by numerical code) in a separate locked filing cabinet held securely. When tests scores are inserted into a computer (password protected files) for data processing and analysis purposes, all patients' data will be stored with their numerical ID only.

2.8 DATA DISSEMINATION

As an integral part of the informed consent process, all potential participants will be informed about the data dissemination intentions (i.e. publications, conference presentations, etc.). They will, however, be informed that no form of data dissemination will take place that might allow them to be identified individually. Data will be presented as group-based data or in such a way as to ensure that they remain anonymous.

No information directly pointing to the identification of any participant will be published without his/her explicit and clear approval obtained in written form. If, for any reason, it was proposed to present an individual case study that might potentially give rise to identification, that individual would be approached for their expressed consent and unless this was obtained, in writing, the proposed dissemination would not occur.

2.9 DATA DESTRUCTION

Although not directly a medical study, because of the nature of the project, all potential participants will be informed, as part of the informed consent process, that data will be held for a maximum period of 10 years as specified in the General Data Protection Regulation from the European Union (GDPR), or deleted at any moment upon a request of withdrawal from participation. After that time, electronic data will be erased and paper/documentation related to that information will be destroyed in accordance with best practice and data protection legislation.

3 REFERENCES

[1] http://ec.europa.eu/research/science-society/index.cfm?fuseaction=public.topic&id=366&lang=1

[2] http://icie.zkm.de/

[3] http://www.i-r-i-e.net/

[4] Research Ethics: http://www.ethicsweb.ca/resources/research/index.html

[5] European Commission: Ethics for researchers, Facilitating research excellence in FP7.

[6] Directive 95/46/EC. 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.

[7] Charter of Fundamental Rights of The European Union. 2000/C364/01. Official Journal of the European Communities 18 December 2000.