Project Title:
Robotic Assistant for MCI Patients at home

RAMCIP
Grant Agreement No: 643433
Research and Innovation Action (RIA)

Deliverable
D2.4. Ethics Protocol

<table>
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<th>Deliverable No.</th>
<th>WP2</th>
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**Authors List**

<table>
<thead>
<tr>
<th>#</th>
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<tr>
<td></td>
<td>Katarzyna Grabowska</td>
<td>KG</td>
<td>LUM</td>
<td><a href="mailto:katarzyna.grabowska@umlub.pl">katarzyna.grabowska@umlub.pl</a></td>
</tr>
</tbody>
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**Co-authors** (in alphabetic order)

<table>
<thead>
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<tr>
<td>1</td>
<td>Dorota Szczesniak-Stanczyk</td>
<td>DSS</td>
<td>LUM</td>
<td><a href="mailto:dorotaszczesniakstanczyk@umlub.pl">dorotaszczesniakstanczyk@umlub.pl</a></td>
</tr>
<tr>
<td>2</td>
<td>Konrad Rejdak</td>
<td>KR</td>
<td>LUM</td>
<td><a href="mailto:k.rejdak@umlub.pl">k.rejdak@umlub.pl</a></td>
</tr>
<tr>
<td>3</td>
<td>Dimitrios Tzovaras</td>
<td>DT</td>
<td>CERTH</td>
<td><a href="mailto:dimitrios.tzovaras@iti.gr">dimitrios.tzovaras@iti.gr</a></td>
</tr>
<tr>
<td>4</td>
<td>Dimitris Giakoumis</td>
<td>DG</td>
<td>CERTH</td>
<td><a href="mailto:dgiakoumi@iti.gr">dgiakoumi@iti.gr</a></td>
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**Reviewers List**

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<td>TUM</td>
<td><a href="mailto:s.endo@tum.de">s.endo@tum.de</a></td>
</tr>
<tr>
<td>2</td>
<td>Ruffaldi</td>
<td>ER</td>
<td>SSSA</td>
<td><a href="mailto:e.ruffaldi@sssup.it">e.ruffaldi@sssup.it</a></td>
</tr>
<tr>
<td>3</td>
<td>Ruiz</td>
<td>AR</td>
<td>Fundació ACE</td>
<td><a href="mailto:aruiz@fundacioace.com">aruiz@fundacioace.com</a></td>
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## List of definitions & abbreviations

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<thead>
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<th>Definition</th>
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<tr>
<td>MCI</td>
<td>Mild Cognitive Impairment</td>
</tr>
<tr>
<td>AD</td>
<td>Alzheimer’s Disease</td>
</tr>
<tr>
<td>UN</td>
<td>United Nations</td>
</tr>
<tr>
<td>UK</td>
<td>United Kingdom</td>
</tr>
<tr>
<td>MMSE</td>
<td>Mini Mental State Examination</td>
</tr>
<tr>
<td>LUM</td>
<td>Medical University of Lublin</td>
</tr>
<tr>
<td>ACE</td>
<td>The Fundació ACE-Institut Català de Neurociències Aplicades</td>
</tr>
<tr>
<td>WP</td>
<td>Work Package</td>
</tr>
<tr>
<td>DSM-IV</td>
<td>Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition</td>
</tr>
<tr>
<td>OECD</td>
<td>Organization for Economic Co-operation and Development</td>
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</table>
Executive Summary

This deliverable has been composed by the RAMCIP consortium in the framework of WP2 “User Centric Requirements and Definition of the RAMCIP System” and its primary scope is to examine ethical issues involved in the RAMCIP project, especially those related to the participation of humans in the project’s pilot trials and overall data collection experiments, establishing a strategy for the project so as to effectively cope with them.

To this end, the present deliverable:

(a) analyses the overall ethical framework of the RAMCIP project, in terms of international and national laws and regulations that are relevant to RAMCIP, with a clear focus on ethical issues of human involvement in the RAMCIP project trials and data security and privacy issues

(b) describes the RAMCIP Ethical Advisory Board that has been established with the purpose of supervising ethical issues in the RAMCIP project and facilitating project partners into addressing privacy issues related to data collection and handling, providing its valuable input and responses to consortium partners involved in the development and realisation of the project experiments, as well as the approach that has been adopted by the RAMCIP project for assessing and managing risks related to ethical issues, throughout the project’s duration

(c) provides the RAMCIP project researchers with a concise “Ethics Manual”, with the purpose to provide them with basic guidelines to facilitate them in their efforts of designing the experiments that shall be conducted in the RAMCIP project, either for data collection purposes to enable the research, development and evaluation of algorithms and methods prior to the development of the final RAMCIP robot, or in the context of the final pilot trials of the RAMCIP project.

The centralized RAMCIP Ethical Advisory Board (EAB) has been set-up in M3 and lodged within an internally monitored service, which provides regular consultation as far as the project’s ethical and information safeguarding issues are regarded. It is tasked with the duty of executing and administering the lawful as well as ethical issues in the entire project procedures, making sure that everyone working in contribution to RAMCIP meets up their respective assigned quota and also the means of regulation for all the pilot participants.

In the contents of this deliverable, the RAMCIP Ethical Monitoring pathway is initially illustrated, by evaluating the ethical challenges that might develop along the line and describing the RAMCIP Ethical Policy. The provision of all documentation and aiding clues concerning the rulings of the nations that are part of the pilots is made. Furthermore, the tasks of the RAMCIP Ethical Advisory Board, as well as other various responsibilities are presented.

Afterwards, Risk Assessment and Mitigation Strategy plans are presented. The threats detected are summarized in the form of a table, while a thorough evaluation of the current safeguarding investigation approach follows, which is explained by a proposed threat specific Risk Exposure Level. In this respect, mitigation planning is described for all threats and risks, with an approximated amount of threats assessed for the entire project already at this early project stage. The outcome of this preliminary risk analysis demonstrates that RAMCIP can be rather considered as a low threat exhibiting project, given the establishment of appropriate mitigation strategies for identified risks.

Finally, the RAMCIP Ethics Manual, a concise outline of basic guidelines that can further facilitate project partners in addressing ethical issues related to RAMCIP is attached in the Annexes section of the present deliverable. Additionally, the provisional ethical approvals that have been obtained from the local Ethical
Committees at the project’s pilot sites (Lublin, Poland – LUM and Barcelona, Spain - ACE) are provided as Annex; these provisional ethical approvals have been obtained over the overall concept of the project and the foreseen project trials. Moreover, a sample of the standard informed consent used in the project’s pilot sites is attached in the Annexes. When the final, detailed protocols of the RAMCIP pilot trials are established, along with the informed consents for human participation in those, after consultation with the project’s Ethics Advisory Board, they will be submitted to the local ethical committees of the project pilot sites, to obtain their final approval.

Finally, it should be underlined that during the project’s lifetime, the RAMCIP Ethics Protocol will be treated as a living document despite the fact that the present deliverable has been initially delivered in M5. In the same respect, risk assessment, ethical monitoring and contingency planning will remain an open concern till the end of the project.
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1. Introduction

The RAMCIP project aims to research and develop a personal care robot capable of supporting older persons with MCI and early stage of AD in their everyday life through proactive and discreet assistance provision. As the envisioned interaction shall take place between a robot and a patient as well as between a robot and health care workers, a series of ethical considerations are required within the project. In particular, ethical aspects such as user privacy, confidentiality, informed consent and user integrity need to be given special attention throughout the project. Important issues to recognize, in any research, as well as in the scope of the RAMCIP project, are the ones of informed consent and data protection. All project partners shall act in accordance with the ethical guidelines of the institutional, national and European conventions and laws from the very beginning of experiments.

The pilot trials of the RAMCIP project will involve observation of the Human-Robot interaction in a specially prepared room at the Neurology Department of LUM equipped with everyday appliances. Moreover, the pilot trials of the RAMCIP robot will involve also controlled sessions of RAMCIP assistance applications that will be held at real homes of end users, under however the supervision of a medical expert from the RAMCIP consortium, who will ensure the safety of the user, as well as the robot.

The validation and evaluation of the RAMCIP paradigm in real houses (Spanish pilot site - ACE) will be performed based on a supervised conduction of pilot operations across selected pilot homes, where patients will be involved in real-life use of the RAMCIP system/platform. Fundació ACE will organize and disseminate to the personnel a complete legal and ethical framework for the real houses trials in cross collaboration with local Institutional Review Board and Ethics Committee and will educate to the personnel to tackle with protection of privacy challenges related to RAMCIP.

In accordance with ethical guidelines and local regulations in the countries conducting pilot trials, all scheduled trials will be overviewed in advance by RAMCIP Ethics Advisory Board and the pilot sites’ local Ethical committees. Any video, voice or cognitive data recorded by the user monitoring modules will be properly anonymised in advance of any distribution to other members of RAMCIP consortium.

Data of human participants involved in certain aspects of the project will be collected, related for e.g. to body motion and daily activities monitored through sensors including computer vision ones, in the context of the project’s WP2, WP3, WP4, WP6 and WP8. More specifically, a series of respective data collection experiments are foreseen to be established within RAMCIP as further described in the Data Management Plan deliverable (D9.3), prior to the development of the final RAMCIP robot, which will provide the researchers with datasets facilitating the research, development and early evaluation of the RAMCIP algorithms and methods. In this scope, as well in the scope of the pilot trials of the overall RAMCIP robot, the consortium will have to comply with any European and national legislation and directives relevant to the country where the data collections are taking place.

1.1 Scope of the deliverable

This deliverable presents ethical instructions that will be followed throughout the project duration and shall guarantee that all decisions taken by the partners in respect to the design and establishment of the project trials, as well as regarding data handling/processing procedures are in accordance with those. The developed ethics protocol shall provide the Consortium with all restrictions and laws related
to RAMCIP, required at any moment to facilitate the project’s research. The issues such as voluntary participation in experiments, informed consent, personal data collection and treatment, and test procedures shall be overseen. The present deliverable should be used as an 'ethics watchdog' for the project.

In this scope, an Ethics Advisory Board (EAB) has been formed to support the Consortium by advising on ethical and privacy issues. Before any user contact and involvement in project experiments, it is obligatory for the experiment’s responsible partner to first submit the test plan to the project’s Ethical Advisory Board and make any amendments deemed necessary by the Board in it. After accepted from the EAB, the test plan shall be submitted for approval and become accepted by the partner’s local ethical board, after implementing any amendments that are deemed necessary by the local ethics committee.

1.2 **Horizon2020 Ethical self-assessment of RAMCIP**

The following table outlines the identified ethical issues related to the RAMCIP project on the basis of the Horizon2020 ethical issues self-assessment checklist.

**Table 1 The RAMCIP H2020 ethics self-assessment checklist**

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<th>1. Human Embryos/Foetus</th>
<th>YES/NO</th>
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<tr>
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<td>NO</td>
</tr>
<tr>
<td>Yes No Does the research involve the use of human embryos?</td>
<td>NO</td>
</tr>
<tr>
<td>Does the research involve the use of human foetal tissues / cells?</td>
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<th>2. Humans</th>
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<tr>
<td>Does the research involve human participants?</td>
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</tr>
<tr>
<td>• Are they volunteers for experiments in social or human sciences research?</td>
<td>YES</td>
</tr>
<tr>
<td>• Are they persons unable to give informed consent?</td>
<td>NO</td>
</tr>
<tr>
<td>• Are they vulnerable individuals or groups?</td>
<td>NO</td>
</tr>
<tr>
<td>• Are they children/minors?</td>
<td>NO</td>
</tr>
<tr>
<td>• Are they patients?</td>
<td>YES</td>
</tr>
<tr>
<td>• Are they healthy volunteers for medical studies?</td>
<td>NO</td>
</tr>
<tr>
<td>• Does your research involve physical interventions on the study participants?</td>
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<tr>
<td>• Does it involve invasive techniques?</td>
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<td>• Does it involve the collection and/or processing of sensitive personal data (e.g.: health, sexual lifestyle, ethnicity, political opinion, religious or</td>
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<td></td>
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<td>---</td>
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<td>philosophical conviction)?</td>
<td></td>
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<tr>
<td>• Does it involve processing of genetic information?</td>
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<tr>
<td>• Does it involve tracking or observation of participants?</td>
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<td>Does the research involve further processing of previously collected personal data (secondary use)?</td>
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<td>6. Non-EU Countries</td>
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<td>Is it planned to use local resources (e.g. animal and/or human tissue samples, genetic material, live animals, human remains, materials of historical value, endangered fauna or flora samples, etc.)?</td>
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<td>Is it planned to export any material - including personal data - from the EU to non-EU countries?</td>
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<td>7. Environment Protection</td>
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<tr>
<td>Does the research deal with endangered fauna and/or flora and/or protected areas?</td>
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<td>Does the research involve the use of elements that may cause harm to humans, including research staff?</td>
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<td>8. Dual Use</td>
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<td>9. Misuse</td>
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<td>10. Other Ethics Issues</td>
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<tr>
<td>Are there any other ethics issues that should be taken into consideration?</td>
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**1.3 Deliverable structure**

The Deliverable is structured and organized in the following chapters:
Chapter 2: The RAMCIP Ethical Framework - this chapter describes the ethical framework of the RAMCIP project, overviewing the international and national laws and regulations that are related to the project’s foreseen end-user studies, with emphasis on topics such as protection of privacy, privacy issues and data gathering in simulated or real house environments of pilot trials, data protection and informed consent.

Chapter 3: The RAMCIP Ethics Advisory Board: The main responsibilities of the project’s Ethics Advisory Board are described. All the members of the project EAB are presented along with brief descriptions of their achievements in the medical field and in scientific areas related to the RAMCIP project.

Chapter 4: Ethics Risk Management- this section presents the Ethics Risk Management Methodology of the RAMCIP project, as well as a table with described potential ethical risks reported by the RAMCIP Consortium members together with proposed mitigation solutions.

Chapter 5: Conclusions - this section provides a general summary of all issues that are discussed within the deliverable.

The deliverable is supplemented by project specific Annexes;

Annex I provides the RAMCIP project’s Ethics Manual, a concise interpretation of the overall RAMCIP ethical protocol into a set of basic, specific guidelines that should be followed by the project partners, to facilitate them into the proper addressing of ethical issues throughout the project’s duration.

Annex II presents the provisional ethical approvals that have already been obtained by the local ethical committees of the project’s pilot trials sites.

Annex III provides a sample informed consent from the project’s LUM pilot site, on the basis of which, the informed consent of the RAMCIP project trials can build upon.

2. The RAMCIP Ethical Framework

The present chapter analyses the ethical framework of the RAMCIP project. This framework involves ethical guidelines that are established with regard to users and participants, to purvey a general ethical framework for end-user studies within RAMCIP, dealing with topics such as protection of privacy, privacy issues and data gathering in simulated or real environments of pilot trials evaluation, data protection, informed consent, etc. Because of the use of personal data and the involvement of human participants in research activities, the RAMCIP project will consider all relevant ethical aspects and will follow the appropriate ethical principles. These principles are in accordance with general national and international policies and regulations. The project will take into consideration of any substantial national, European, and international regulation and institutional code connected with the countries taking part in the research. The Consortium of the RAMCIP project will devote itself to conform to the relevant national legislation, in addition to the ethical protocol created within the project. The most important issues in international and national policies and legislations are:

- **Voluntary Participation:** participants will be allowed to take part in the project only on a voluntary basis which means that every person freely and willingly agrees to participate in RAMCIP studies without compulsion.

- **Informed Consent:** RAMCIP will gain informed consent from volunteers before participating in the studies to sustain the right and dignity of those participants. The rules of good scientific study will be followed during the project. An indicative sample of informed consent used by the LUM partner, which will provide a basis toward the development of the project’s informed consent forms that will be used in the trials, is provided in Annex III of the deliverable.
- **Data protection:** RAMCIP project has developed a plan (see chapter 3 and Annex I of the deliverable) to deal with personal data gathered during the research.

- **Supervision:** In some countries, empirical studies will have to be approved by ethical committees and the RAMCIP project will work in accordance with them. It was agreed that the entire project work will be submitted to the local Ethics Committees in Poland and Spain for the provisional approval, already at early project stages. This process has been successfully concluded; the obtained provisional approvals from the LUM and ACE local ethical committees over the overall concept of the project and the foreseen project trials are included in Annex II of the deliverable. At a later stage, when the details of the RAMCIP project trials will have been specified, the final ethical approval for the project trials will be obtained from the committees, prior to their realization. All further data collection experiments of the project should be submitted to the respective local ethical Committees for ethical approvals prior to their realization.

- **Human integrity:** In order to preserve the physical and emotional integrity of users when participating in research and interacting with the RAMCIP solution, all relevant processes and regulations as listed in this chapter will be followed.

### 2.1 International Policies and European Union Regulations

Many reports and guidelines recognizing human ethics in research are derived from many historical events that identified the need to protect the users. The Nuremberg Code of 1949 is one of the examples of those documents and is considered to greatly contribute to ethics in research involving humans. There are 10 fundamental principles in this document that should be considered when carrying out research with humans.

1. The voluntary consent of a participant is crucial.
2. The results of the research should serve the good of society.
3. The experiment should be designed in a way that anticipated results will justify the performance.
4. The experiment should be carried out without unnecessary mental and physical injuries or harm.
5. If there is a risk of death or disabling injury, no research should be conducted.
6. The level of risk should never be higher than the importance of the problem to be studied.
7. Proper facilities should be provided to protect experimental subject against any possibility of injury, disability, or death.
8. The staff who conduct or take part in the experiment must be fully trained and scientifically qualified.
9. Volunteers must have the right to leave the experiment at any time.
10. The scientists who are in charge of the experiment, must be prepared to cease it at any time if there is a belief that the continuation is likely to result in injury, disability, or death of the participant.

The Nuremberg code sets the authoritative example for the future studies involving human subjects. Many institutional and international ethical guidelines were developed upon these 10 principles. Others regulations and legislations that have contributed to basic ethical guidelines in experiments with human subjects are for example: the Declaration of Helsinki (1964 and subsequent revisions), the

These documents and many more, redounded to the appearance of general ethical principles. They are perceived as essential rights in Europe and worldwide, such as protection of human dignity and human life, protection of personal data and privacy as well as the environment. Partners will carefully observe the Charter of Fundamental Rights of The European Union, published in the Official Journal of the European Communities (2000/C 364/01), the Convention for the Protection of Human Rights and Fundamental Freedoms (1950), the Handbook on European Data Protection Law (2013), European Code of Conduct for Research Integrity and the European Charter for research. The values described in these documents include, but are not limited to:

- Protection of personal data
- Right for Private and Family Life
- Freedom of research
- Respect of Human Rights
- Informed consent of participants
- Physical and moral integrity of individuals involved

RAMCIP will also consider the opinions of the European Group of Advisers on the Ethical Implications of Biotechnology (1991 -1997) and the opinions of the European Group on Ethics in Science and New technologies (as from 1998).

All the national laws of the countries involved in the project and the European laws that are relevant to RAMCIP shall be taken into account throughout the project. In this scope, this section describes the international legal and ethical sphere of the RAMCIP plan.

### 2.1.1 Directive 95/46/EC (amendment 2002/58/EC) – EU

**Chapter II – Section I – Article 6**

Personal data provided by Member States must be:

1. altered legally and justly
2. gathered for particular, clear and reasonable purpose and shall not be further modified or processed in an inappropriate way. Further processing of data for statistical, historical or scientific purposes are acceptable only if partners guarantee suitable protection
3. stored in a way which allows identification of data subjects for no longer that it is necessary to use them for the purposes of the project or further processing. All members of RAMCIP project should provide suitable protection for personal data collected for longer periods of time for scientific, historical or statistical usage
4. sufficient, compatible and not redundant in connection with the purposes for which they are gathered and/or further altered
5. strict and, if necessary, kept up to date; every imprecise or fragmentary data must be removed or improved if they are in conflict with the purposes for which they were collected

**Chapter II – Section II – Article 7**

State Members shall ensure that the data may be processed only if:

1. the consent has been obtained from the subject unequivocally
2. the protection of the vital interest of the data subject needs processing
3. the conduct of a task performed in the public interest or in accomplishment of official authority settled in the controller or in a third party to whom the data are revealed needs processing
4. processing is inevitable for the means of the legitimate interests proceeded by the controller or by the third party or parties to whom the data are revealed, with the exception of a situation in which interests are abrogated by the interests for vital rights and freedoms of the data subject which demands protection
5. processing is needed for the conduct of a contract to which the data subject is partaker or due to initiate the data subject into a contract at his/her request
6. compliance with legal responsibility, to which the controller is subject, may be achieved only by processing

**Chapter II – Section IV Article 10**
Information in cases of collection of data from the data subject
State Members shall ensure that the executive or his/her representative gives a data subject from whom the data will be collected at least the following information:
1. the identity of the executive or his/her representative, if any
2. the aims of the processing for which the data are destined
3. any further information such as: the receivers or categories of receivers of the data, if answers to the questions are required or voluntary and the potential consequences of failure to reply, the presence of the right of access to and the right to correct the data having in mind the specific circumstances in which the data are gathered

**Chapter II – Section IV Article 11**
Information where the data have not been collected from the data subject
In a situation where the data have not been collected from the data subject, the members of the project shall guarantee that the controller or his/her representative at the time of performing recording of personal data, or if there is disclosure to a third party, provides the data subject with at least the following information:
1. the identity of the executive or his/her representative, if any
2. the aims of the processing
3. any further information such as: the categories of data concerned, the receivers or categories of receivers of the data, the presence of the right of access to and the right to correct the data having in mind the specific circumstances in which the data are gathered

Paragraph 1 shall not be considered where the arrangement of such information appears to be impossible or would demand inadequate effort or if recording or revealing has its grounds in law. In such cases members shall provide suitable protection.

**Chapter II – Section V Article 12**
Subject shall have the right to gain each data from the executive:
1. without restraint at reasonable intermissions and without redundant delay or expense:
   - affirmation if the data connected with him/her are being processed or not
- the receivers or categories of receivers to whom the data are disclosed
- information in explicit form about the data being processed and of any applicable information as to their source
- insight into the reasoning involved in any automatic processing of data connected with him/her

2. as suitable the modification, cancellation or obstruction of data the processing of which does not follow the arrangement of this instruction, especially when the data are fragmentary or of inappropriate nature
3. reporting to third parties who have been disclosed with the data of any modification, cancellation or obstruction carried out in compliance with, unless it appears impossible or requires inadequate effort

**Chapter II – Section VII Article 14**

Data subject shall be granted the right:

1. to oppose to legitimate sources referring to his/her particular situation to the processing of data referring to him/her. If the objection is rationalized, the processing may no longer contain those data
2. to disagree on the processing of his/her personal data for the commercial use or to be informed before the data are shown to the third parties for the first time or used on their behalf for the commercial purposes (the objection shall be free of charge)

**Chapter II – Section VIII Article 16**

The personal data must not be processed by any person who has access to it and is working under the authority of the controller, unless he/she has been instructed by the controller or it is required by law.

**Chapter II – Section VIII Article 17**

1. All State Members shall ensure that the controller uses suitable technical and organizational methods to secure personal data against unexpected or illegal devastation or lost, modification, illegitimate access, especially when the processed data are connected with the transmission through network, and against all other forms of illegal use. The methods used shall be at the level of protection suitable to the risk defined by the processing and the character of the data.
2. State Members should guarantee that the executive chooses a processor providing adequate assurance in accordance with the technical security and organizational methods administrating the processing to be performed, and it must ensure conformance with those methods.
3. The performance of processing by a processor must be conducted by a contract or a legal act entailing the processor to the controller and deciding on conditions that: processor works only under the instructions from the controller and the law of the country in which the processing is carried out.
4. Contract or the legal act referring to data protection and the conditions related to the methods described in paragraph 1 shall be in writing or in another similar form.

**2.2 National Laws and Regulations**

Apart from international regulations, RAMCIP's partners will conduct research according to community laws as well as national conventions. The user studies
will take place in Spain, Germany, Poland, Italy, Greece and Great Britain where respective national laws apply.

The RAMCIP project and all its partners will act in accordance with the legal regulations and the guidelines showed by the European Union and all participating countries. The table below presents the identified national codes of conduct and laws for the protection of data and human integrity, including all subsequent and future amendments that may appear.

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<td>- Subject Insurance during pivotal clinical trials. Ley 29/2006, de 26 de julio, de garantías y uso racional de</td>
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2.3 Data Security

In the RAMCIP project, all reports and transcripts will be private; all the materials gathered through user studies will be treated as non-identifiable. The personal information about the volunteers will be kept in confidence and will be made anonymous. In order to keep identities of RAMCIP participants uncovered, personal identifiers will be replaced with a numerical code. There will be no possibility to associate identification code with the name of a participant. It is commonly known that the usage of physiological data may potentially provide information on the wellbeing of the participants; hence the RAMCIP project members are responsible for considering how to make that information available to the participants. In the case when individual notification is allowed, data's custodian will have to take all reasonable steps to re-identify those data to each participant.

The experimental data will be electronically recorded and processed. The material will be stored on computers which will be specially protected from intrusive access. Only authorized members of the Consortium will have access to these data. Participants’ names will not be given in any publication. Visual materials used in presentations or publications will be modified to avoid any identification of participants with mental impairment since it can reveal sensitive health information. The pictures of faces of healthy participants may be published only on the basis of appropriate consent to data publication. The personal data collected in the project will be used only for research purposes and the use for commercial purposes is strictly forbidden.

2.3.1 General principles

Confidentiality is of paramount importance in handling of personal information. Therefore, database managers and registry administrators should make it an obligation, ensuring that holding and using of personal information and data should only be done when a certain level of agreement has been reached with the owner of such data.

In the process of managing data effectively, all data miners, analysts, as well as investigators should fully consider the points of view below:

- **Clues** on recklessly or purposely exposing the names and status of members in RAMCIP trials is totally disallowed during investigation, with a lack of proven declaration of members.
- **Circulation** of information with associates
- **Access** to information
- Determining and securing proper form of access, data configuration, database-archive style and format; be it in hard (paper) or soft (electronic) forms, consisting of information management, analyses, investigation and inquiry communications.
- **Safeguarding** information inside the system which is made up of staff, contractors, volunteers and others all through the entire procedure such as investigation outcomes, inquiry, exchange of information, etc
In addition, members and associates should possess the capacity to handle the circulation of the gathered information. The analysts or investigators are empowered to broadcast clues or any information only with all forms of identification concealed. In essence, vital characteristics such as age and sex only can be made publically available. Confidential details such as name and address should be stored by authorized personnel at a particular section (within a secured password file), just for the time that the data needs to be processed; this information shall later be wiped out.

Although the typical regulation formulates important assumptions, it is not stated when personal details could be revealed to the rest in the investigation. 

**People and organizations handling private and personal data should be liable in determining what is right and proper as well as on variety of issues respectively (Medical Research Council, 2000).**

**Individuals and organizations using confidential information have to take responsibility for deciding what is justified and acceptable also on a case by case basis (Medical Research Council, 2000).**

Just as stated earlier, safety of personal information also entails letting the members aware of what could happen with their details such as allocation of information. As databases are built, securing private data can be made more and more difficult. Taking away participants identity and substituting them with codes does not assure total confidentiality. Thorough inspection of details, as well as effective pre-processing to cater for data confidentiality in databases would be ensured by the Ethics Advisory Board. The omission of identifying details from collected information about a person could be insufficient to anonymize the identity due to the fact that there is possibility to recreate details of identity from various forms of information.

In RAMCIP, participants are informed about the possibility of disseminating their details, although only unacknowledged and anonymous details can be shared. Certainly, there are quick fixes to the problems that arise from handling private information such as substituting names with digital numbered codes, accumulating information so that personal performance measures are not at hand, coding and encrypting information to ensure that those administrators in charge and in need of detailed information could have them after going through a process of requesting and signing a form of legal tender, agreeing to ensure that all forms of privacy and confidentiality concerning the individuals are kept intact.

To summarize, a series of RAMCIP decisions in the scope of personal data handling and protection are as follows:

1. The use of unacknowledged data which still remain out of the public sphere and the use of traceable personal information needs to be verified and approved by the Ethics Committee on Investigation and Research.
2. All personal information needs to be encrypted and placed incognito in line with the needs of research, as well as of information processing. Personal attributes that are very important should be the only information to be kept.
3. The decision on the disclosure of personal details and information is the responsibility of the individuals whom the information has been entrusted with.
4. Confidential information should be managed on by the member staff with commitment to confidentiality during pilot trials.
5. Ensuring personal responsibility during supervision, training procedures, trials and information protection setup is one of the tasks of the manager...
of the study site, with enough privileges to counter unauthorized breaches and cracks of understanding.

All the above principles are in accordance with the Medical Research Council (2000).

2.3.2 Privacy Protection and Coding

To ensure that sensitive details are not divulged, all sort of information provided should be protected. Privacy protection creates a barrier and firewall against malicious, unwanted and unauthorized exposure of private and classified information.

Private and classified information could be altered to hide their true meaning by applying various techniques:

- **Information coding** consists of details which could be normally identified by anyone, but their true meaning has being hidden using some sort of coding technique. Such coding technique, its understanding and application are known to the research and investigation team in charge of the information.

- **Encrypted Hyperlinked** details to private information are also concealed to the research and investigation team that manages them, as it also possesses encrypted data that could determine individuals. Data administrators and managers are the ones in charge and the protector to the decryption code to large research and investigation databases.

- **Encrypted non-hyperlinked** details do not hold data with vital and classified detailed information which might be useful in the determination of individuals involved.

In the least possible form, such encrypted details should not consist or encode any of the listed below:

- Full name, contact address, post code, email address, telephone numbers, fax numbers.
- Social security, id number, passport number, driving license number.
- Details of next of kin or photographs

Of course, there are possibilities in determining private data of individuals involved with both the encrypted hyperlinked and encrypted non-hyperlinked details by compilation. The core and vital attributes in doing so might be:

- Age, by taking small samples, and in such cases, certain level of agreement is reached on the precise level of science and the safety of the confidentiality involved.
- Therapy and uncommon illness, in situations when such ill health or disorder is noticeable.
- Uncompleted postal address or postal code.
- Location of the hospital and treatment center.
- Unusual employment and job location.
- Merging birth place, race, ethnic background and date of death.

Database designers and investigators, when creating databases are supposed to always perform a proper review before disseminating such information as well as before any details are included in publications- making series of checks to be certain that publishing information would not be traced or linked to any person or narrowed to a specific group of people. Verifying as well as ascertaining the amount of details which are safe to add and will not give a clue on link to any person or narrowed to a specific group of people and ensure that the outcomes they produce are only determined by samples considering the cases at hand,
which will eventually determine the manner in which the outcomes in the publication are applied (Medical Research Council, 2000).

In the context of RAMCIP, it is best to apply the encrypted non-hyperlinked details policy, without users with uncommon illnesses and any other forms that are easily identifiable. After the encryption process, such data shields all forms of link and traceability to the real and original source, totally concealing the details of the members and other participants involved in the process.

2.3.3 **International and European Instruments in the field of data protection**

At the Council of Europe Convention for the protection of individuals, atomization of private data was the first European mechanism in the area. This body presented the fundamental ethics for legal information handling and also discussing the challenges aligned with information system attacks that may be experienced, like information harvesting and data gathering, at a particular time. As a matter of fact, it is majorly about automatically processing information, despite participating nations having the tendency to prolong its suitability to a non-automated data processing system. Art. 6 states that medical data may not be processed automatically unless local regulations issue relevant means of protection. After the passing the EC Directives on Data Protection, the meeting was on any valid purpose for EU participating nations.

According to the Charter of Fundamental Rights, the policy of independent authority of all corresponding lawful tendencies is stated in a different article from the one on safeguarding of private information. Article 8 clearly highlights the proper legitimacy to safeguarding the private information of a person and also the safeguarding and privacy of all private information which currently possesses legitimate grounds, asides from the proper and morally expected obligation for a person’s private life and the protection of dignity of every human being. Art 8 of the Charter distinctly highlights the mode of acceptable processing of private information, knowing that such processing would be moderate and presumed reasons base its notion on the compliance to the data specimen or other allowed forms acceptable by the laid down rules and regulations. Some quotations are later made equal to the right of the specimen in details and could be the authorization to use information and as well as to fix, improve or amend such information. Lastly, the Art. 8 presents the reason and purpose for which conforming to the data protection law could be controlled.

The Council of Europe in the year 1999 embraced the proposal on the instructions concerning the protection of privacy in the information path. This set of instructions may be integrated in or adjoined to the codes of operations of the Internet services provider in order to get lawful validation. The proposal contains a string of well detailed information as regards guiding all its users, readers as well as provider of services on what measures to be taken when incident arises especially in the reduction of risk that occur through using the cyberspace. Importantly, it should be remembered that all those trying to gain access are expected to tender a digital signature and follow basic encryption techniques. Also, the service providers are mandated to apply certified privacy statements on the internet portals. Lastly, the dissemination of classified information, take for example medical information, report for business purpose that initially required, well known and accurate understanding of the information details in discussion.

As mandated, the OECD is much involved in all matters concerning safe guarding information and data protection on the World Wide Web. It also addresses and deals about safeguarding the rights of users and the consumers in connection to e-business. From the beginning, OECD announced a set of instructions to
safeguard and supervise confidentiality by laying down the basic and most essential foundation needed (OECD, 1980).

The OECD in the year 1998 made a proposal public in connection to the instructions mentioned above on a universal scale. This set of instructions aims and focuses its concentration on online web-portals offering consumables goods and business services like holiday travel ticket sales, tours and tourism, trade etc. Although most of these are not lawfully agreed upon, until the service provider of the Internet clearly specifies such conditions. Though, such instructions are not related to healthcare applications, arrangement of it may duly apply.

The instructions make it mandatory to every web-portal as well as website services provider to always create a link to an enacted regulation on confidentiality, data protection and the Confidentiality and Data Protection Authority. Besides, all Confidentiality and Data Protection Authority need to be made available on Internet via valid, properly written, well designed and interactive portals. The Internet portals are also expected to have a statement of confidentiality and privacy and designated places on them to acknowledge the information provided and being collected, its purpose and use as well as others conditions they are subjected to, with an option to discontinue if they do not accept such terms and policies. Alert and cautioning information on threats faced on the Internet should be issued in all circumstances involving the collection and processing of confidential details. For classified information, a sophisticated level of security is expected to be placed, such as the utilization of upgraded privacy and confidentiality technologies should also be a requirement. Therefore, online portals should correctly stipulate the acknowledgement of totally burden for the safeguarding and confidentiality of individual private details received and processed by them. In all concerning a subject details and data rights, the instructions shows the privilege to have online the data gathered and kept precisely as well as the other way round, for example; online streams or paid-for-profiles.

2.3.3.1 Data Protection Drive 95/46/EC

The EC Mandate on the protection and safeguarding of private data was adopted by Council in 1995. The recognition of laws dealing directly in connection to the right of privacy and confidentiality was the first attempt of the mandate on the EC level. Its applicability to both the public and private spheres are some of the core components of the mandate, as well as to automated and non-automated data processing systems which has reliably safeguarded ordinary people in contrary to lawfully mandated persons. Furthermore, the information and details are expected to be a part of the archival system that could be accessed using specific criteria. So far it meets the set of standard required to create an individual profile from provided data.

It does not matter if the procedure is automated or not, what is important is that the mandate controls the processing of individual information.

**Scope**

Personal Data could be defined as “a piece of detailed information which describes or determines and individual ordinary person ('data subject'); in whatever way, an identifiable individual is a personality that could be identified by association or in relation to any form of identification which could be in form of a number or other factors distinct to clearly noticeable bodily, physical, other physiological, mental, cultural or social identity.” (Art. 2 a).

Although, the definite explanation should be broader than what is presented here, “personal data” could be defined further as the capacity to be competent in tracing a piece of information to an individual, even supposing the individual holding such piece of information is not able to trace such. A few examples of
such personal data are: statement of bank account, credit card number, address, criminal record.

The understanding of processing could be defined as “an activity or set of activities which are performed and implemented on individual data, even if or not by means of automation, for example recording, alteration and adaptation, collection, consultation, use, disclosure by transmission, retrieval, dissemination or contrarily fabricating possible adjustment or consolidation, blocking, deleting and eradication; (Art. 2 d).

The power of conformity lies within the authority of the "controller”, which means the natural or artificial person, group of individuals, agency, civic authority or any other body that could regulate the reason and purposes of personal data processing either by working alone or together with others with similar mission; (Art. 2 d).

The data protection regulations are useful not only when the controller is rooted in the EU. It is also needed each time when the controller operates any system located in the EU for data processing reasons. (art 4). However, foreign controllers not from the EU but who process data within the EU, are obligated to follow a strict data protection rule. It is assumed that all online e-commerce portals citizens of the EU patronize would be processing personal data and at some point during this process would have to use systems in the EU to complete such data processing e.g. the clients’ computer. As a result, such web portal operators are obligated to comply with the European data protection regulations. The instructions were in place before the popularity of the Internet and this subject attracted not enough decree and legislation until the present.

Principles

Individual data are to be left unprocessed in its entirety until the conditions set are fully met. These conditions are classified into three different groups; transparency, legitimate purpose and proportionality.

Transparency

Owners of details and process data deserve to know that their personal data are being processed. It is the duty of the controller to ensure that adequate and up-to-date information about him or her such as reasons, purpose of data processing, including contact details; name, phone, email contact and address, data of beneficiary as well as all needed information to secure smooth and fair processing (art. 10 and 11).

Data information could be handled in the following situations (art. 7);

- If the data owner has issued an authorization of any form
- If the processing is required to conduct or getting into certain forms of agreement
- If the processing is needed for safeguarding the major concern of the data owner
- If the processing is needed to conform with an agreed legislation
- Processing is also important for proper conduct of various works done for the community or in the course of carrying out formal obligation of the controller or in an observer or mediator that disclosure of data has been revealed.
- Processing is also important when the controller is considering and pursing genuine concern or by an observer or mediator or other entities that data have been revealed to, and exempting only cases where such genuine concerns are disregarded due to basic rights, essential norms, freedom and privilege of the owner of data.
The data owner has the privilege to access all data about him or her in details. The data owner has the authority to request for amendments, omission, cancelation or barring of details that are insufficient, defective or are not being processed according to the standard rules of confidentiality and data protection (art. 12).

**Legitimate Purpose**

Individual information is only processed for particular, exact and justifiable purposes, and the processing may be aborted at some point if unsuitable with the core aim (art. 6 b).

**Proportionality**

As far as it meets the basic requirement, individual information could be subjected to processing if it is proper and not exorbitant in affiliation to the reason why they are gathered and processed. All considerable steps needs to be taken to make sure that all insufficient or defective information, which are likely to be conflicting with the core aim of the data collection in the first place, must be amended or deleted. Participating nations are expected to present the proper and a more relevant protection for individual information kept in the archives in the long term specifically for factual, scientific, demographic, experimental or real-time purposes (art. 6).

Whenever any precise and somewhat sensitive information is processed, further restraints may be administered (art. 8).

At any point in time, the information owner has the right to doubt and challenge the process of their individual information used for financial gains and profit making purposes (art. 14).

The judgments that yield outcome or greatly influence the information about the owner are not established exclusively on the automated processing of data (art. 15). If automatic decision processing will be deployed as a part of the system, a special application and petition form are needed to be made available.

**Supervisory authority and the public register processing operations**

Every participating nation should create a body responsible for supervisory role and be empowered to do so. Such body would be independent and guide as well as safeguard data in each participating member state, issue guidance to authorities on capacity of management as well as supervision needed, and able to execute lawful matters when data protection regulations are breached and disobeyed (art. 28). The body also entertains complaints coming from natural persons on breach of regulations or such complaints could be made in any tribunal or court of justice.

The controller is expected to inform the supervisory body prior to the start of data processing and the information expected should contain the following information details (art. 19):

- Controller’s full name, contact address and that of any other representing agencies, if any;
- The specific reason and aim of the processing;
- A detailed insight type and description of data owner and of the information and the alliance that brought them together;
- All third parties and any other aspect of receiver that such information might have been leaked to.
- Recommended dissemination of information to other recipients;
- A broad narrative description of the process to ensure that a proper safeguarding pattern is followed for data processing.

Such information as this is secured mostly in municipal government roster.
2.4 Ethical Issues of human involvement in the RAMCIP project

These are several ethical and legal issues related to human involvement in project trials, which will be considered in RAMCIP:

- **User Integrity**: User research should not allow the exposure of volunteers to more than a minimal risk. However, it is unlikely that user studies in the RAMCIP project will expose participants to any danger, as further explained in Section 2.4.3 below (safety issues).
- **Informed Consent**: This form delivers the crucial information for volunteers about the background of the research they will take part in and the rights entitled to each volunteer related to their personal data and physical/emotional integrity.
- **Comprehension**: The specialists need to ensure that each participant is aware of what is involved in the user study. It must be done in a way which is completely clear to the user. It also needs to thoroughly cover the ethically relevant information on the informed consent.
- **Voluntariness**: All participants will be allowed to take part in the experiment only on a voluntary basis. This means that each person freely and willingly participates in the study, without any coercion. Furthermore, as the attitude of the person who conducts the study may influence participant's attention, s/he must behave in a way that would not rush the volunteers into making their decisions.
- **Participant’s rights**: The recognition of human rights varies in different countries. Although in many cases there is a general agreement, definition and interpretations of those rights vary. That is why the RAMCIP consortium will consider a) European rights and b) national rights of particular countries in which trials and tests will be conducted.
- **Confidentiality**: When the product is in any way confidential, participants need to be aware that they cannot talk about it or give their opinion of it.
- **Privacy**: Privacy is related to the way the data about the participants will be stored. When the volunteers are signing the informed consent this information is available for them.
- **Waivers**: Participants should give a permission to use materials such as questionnaires, audio and video recordings (and their transcripts).

Crucial ethical issues for the RAMCIP trials are discussed below in detail. These are: informed consent, data security, participation guidelines and rights, conflict of interest, safety and gender issues.

2.4.1 Informed Consent

**Inclusion criteria** for end-users are a volunteer adult patient (male or female patients ages 55 to 90 years old), capable of communicating with the research team, having normal physical examination, normal laboratory tests evaluations and diagnosed with MCI or mild AD (see Section 2.4.2 below for more details). A specific recruitment procedure will be used for the end-user involvement in WP8 for the Polish and Spanish user studies, whereas similar procedures should be followed for the further data collection experiments of the project as well. Firstly, the general issues and aims of RAMCIP will be presented to the potential participants and they will be invited for a meeting to gain further information. During this meeting, detailed information about the research will be given to the volunteers (including issues such as: why do we think s/he would be a good participant, what do we expect from them, what they will receive, and main study's goals. If, after the presentation, they are still interested in the project,
they will be offered an informed consent to read, which will be also further explained by the trial responsible when necessary. If the volunteer is willing to take part in the study, the consent form will be signed by the participant and the study’s principal investigator or her/his official delegate. Each participant will get a copy of signed informed consent and a copy will stay in the project files. The form of the informed consent has to be accepted by the local Ethics Committee of the trial site prior to its utilization and it needs to be prepared in local languages for better understanding.

Our foreseen experimental device of the project’s pilot trials is classified as a personal service robot and until now there is no suitable regulation which explicitly provides guidelines on how to conduct end-user studies for service robots. In Poland it was decided to conduct the entire evaluation as research experiment conducted by medical doctors as described in the Act on 5 December 1996 on the professions of doctor and dentist.

There is no purpose of involving disabled persons or children in RAMCIP user studies. Nevertheless, this kind of contact may appear in medical settings. RAMCIP cares about the mental integrity and well-being of these individuals on physical and psychological levels. Any interaction with the RAMCIP project in the scope of the project trials shall be inoffensive and trustworthy, by being fully stable and predictable.

Informed consent is used to provide participants of a study, trial, interview or training with the information about the research in which she/he is going to take part in. The source of it lies in the legal and ethical right of the participant to know what happens to her/his body and personal data. It is also connected with the ethical responsibility of the investigator to let participant in on the experiment. The need to obtain the consent of a volunteer to take part in the research mirrors the right of a volunteer to autonomy and also her/his privilege to be free from harm (physical or psychological) and to keep her/his personal data confidential. These are ethical rules identified by law as legal rights. There can be defined three elements of the informed consent: the information conveyed, the ability to understand it and the voluntariness of any decision made.

Respect for volunteers means that participants have the freedom to choose what shall or shall not happen to them. This freedom is implemented when sufficient requirements for informed consent are covered.

2.4.1.1 Basic elements of informed consent

All researchers of the RAMCIP project will obtain informed consent from the subjects only in a situation in which participant is given a satisfactory opportunity to deliberate whether or not to take part in the study and in which the probability of compulsion or inappropriate impact is minimal.

The given information shall be in a language understandable to the volunteer. Any form of informed consent must not contain condonable language which would make participant or the researcher forgo some of the participant’s legal rights. What is more, it shall not unbind the researcher, the sponsor or the institution from responsibility for carelessness.

According to the American Psychological Association (2002), when obtaining informed consent, it is necessary to provide participant with the following information:

1. The procedures of the research, the expected length, and the purpose
2. The potential discomfort, adverse/side effects, and risks
3. The explanation of possible benefits to the participant or to the others which might be expected from the experiment
4. Information about the confidentiality of the data
5. The right to withdraw from the study at any moment and the possible consequences of it
6. Where to seek for help if any doubts or questions about the research or participant’s rights emerge

Additionally:
- The participants should be provided with suitable insurance or repayment when taking part in trial
- Potential risks and legal binds of using certified sensors and/or software (as well as their prototypes) shall also be provided to the participants

If applicable, the following information should also be provided to participants:
1. an explanation that some procedures may generate risks which are unpredictable at the moment
2. expected situations in which volunteer’s participation may be cancelled by the investigator regardless of the participant’s consent
3. the consequences of participant’s decision to leave the experiment and procedures of restrained termination of participation
4. an explanation that during the research new discoveries may occur and they may influence participant’s willingness to continue the participation
5. the estimated number of participants taking part in the studies

2.4.1.2 Guidelines for compiling the informed consent form

The following clues may help investigators on how to provide information to volunteers and therefore gain proper informed consent:
- Informed consent is a procedure, not just a document. The presented information should allow a person to voluntarily make a decision about the participation in the RAMCIP project and the specific trial at hand.
- The process of gaining informed consent is created to inform participants about the research using terms and phrases so they can understand about the study. Thus, the form of the informed consent and its documentation must be written in “layman’s language” (i.e. understandable for participants). The presentation of written information is used to document the foundations of consent and for the participant’s future remark. The consent document will be improved if any defect is noted or when the additional information will enhance the consent process.
- The investigators should avoid the use of the first person (e.g. “I hope that...”) since it may be interpreted as suggestive, may be treated as an alternative for the factual information, and may represent forcible influence over a volunteer.
- It is inappropriate to use specialized scientific language and legalese. The informed consent is mainly treated as an educational tool, not as a legal form.
- Any possible experience that may occur throughout the studies shall be described.
- Throughout the research some predictable inconveniences, harms and risks may appear thus all participants will be informed about them. The consent process and documentation shall be improved every time a new risk appears during the conduct of the experiment.
- The description of profits that participants may expect will be prepared. There is a possibility of existing only a benefit of helping the public at large. If there is a need for payment for participation, it cannot be
imposed and the participant should be allowed to choose the method of handling.
- The terms of keeping personally identifiable private information of participants will be also defined and given.
- In case of possible study-related harm, participants will be provided with an explanation of whatever repayment or medical care will be given.
- There is no possibility of rejecting any legal rights of participants. The volunteers should not get the impression that they are left without seeking satisfaction beyond the voluntary limits.
- Participants will be given details of contact people who will be ready to answer all questions concerning the experiment, participant rights, and study-related harms.
- There will be different people able to answer questions in particular areas to avoid a conflict of interest. The questions about the research will be answered by investigators. An on-site doctor/psychologist will be answering questions about participant rights or potential study-related injuries. All contact information with local telephone numbers will be given in informed consent document.
- Taking part in the experiment is voluntary and the participant has the right to leave it at any time. It should be emphasized that there is no punishment or loss of profits in case of not participating or withdrawing of the research.

2.4.1.3 Informed consent concerning the use of personal information
According to the definition of the OECD (Organization for Economic Co-operation and Development) and the Directive 95/46/EC, personal data will be recorded within RAMCIP. A short explanation of the type of data which will be collected, is described in chapter about data management. Each participant will be given full information about:
- The purpose of research
- What type of data will be documented, collected and for what purposes?
- Will the data be transferred?
- Who will own the data?
- Are the data related to other information?
- Will the data be used for commercial purposes?
- For how long will the data be stored?
- The place of storing the data and the national legislation behind it
- Who will have an access to the data?
- Who will be in charge of protecting the data?

2.4.1.4 Methodology of collecting the Informed consent documentation:
Informed consent should be documented in a written form, accepted by the RAMCIP Advisory Board and signed by the participant or his/her representative. A person signing the consent shall be given a copy.

Research participant's identity
A participant will be filling this part.
The original document will be held by the investigator and the participant will be given a copy of it.
**Participant Consent Form**
A participant will be filling this part.  
The original document will be held by the investigator and the participant will be given a copy of it.

**Investigators’ confirming statement**
The investigator will be filling this part.  
The original document will be held by the participant and the investigator will keep a copy of it.

**Illiterate participants**
In exceptional cases the informed consent may be given in an oral form in the presence of at least one witness, as described in national legislation. The person signing the consent is the witness.  
This form is going to be translated into the national language of the country in which the research will be carried out. The template will be accommodated to the local specificities of each national ethical committee.

**People with cognitive impairments/learning difficulties**
The persons of this category that are foreseen to be involved in the RAMCIP trials are expected to fully understand the informed consent content. If however, in some cases, they are not capable of doing it, no study will be carried out as per RAMCIP Grant Agreement.

2.4.2 **Participation Guidelines & Rights**
RAMCIP interaction scenarios could be considered to create a risk for the physical integrity and wellbeing of its human participants on a theoretical level. The researchers will carefully analyse any possible harmful obstructions that may occur during an interaction between the human participant and the robot device. Yet, in RAMCIP this kind of contact is expected to be minimal. Particular attention will be paid to the means of worst-case scenarios avoidance. Different sensors and controlled mechanisms will be used for immediate interruption of the tests, if needed. What is more, there will be also a professional who will be controlling and monitoring the device throughout the experiment.

2.4.2.1 **Selection of Participants in the RAMCIP pilot trials**
Selected individuals from Spain and Poland will be obtained from a database of previously diagnosed subjects, existent at the two pilot sites (LUM for Poland, ACE for Spain). Thus, Screening will be held in databases of previously diagnosed patients. Only patients diagnosed with MCI or Mild AD according to international criteria will be eligible and invited to the trial, whereas selected subjects will have full legal capacity so they can sign an informed consent Participants’ selection will be based on specific inclusion and exclusion criteria, as the ones described below.

2.4.2.2 **Inclusion Criteria**
General Requirements
- Male or female patients aged 55 to 90 years old.
- The patient is capable of communicating with the site personnel
- The patient has normal physical examination and normal laboratory tests results, or abnormal findings that are not clinically significant.

Cognitive disorders criteria
- Has an MMSE score of 20 through 26 at Visit 1 (Folstein et al. 1975; detailed in Attachment 3).
- Has a Geriatric Depression Scale score of < 7 (on the staff-administered short form).

2.4.2.3 Exclusion criteria
- Lack of the patient's informed consent.
- Does not have a reliable caregiver who is in frequent contact with the patient (defined as at least 10 hours per week), will accompany the patient during the trial and will monitor robot-patient interaction.
- Lacks, in the investigator's opinion, adequate premorbid literacy, adequate vision, or adequate hearing to complete the required psychometric tests.
- Severe Apathy
- Has current serious or unstable illnesses including cardiovascular (including unstable ischemic cardiovascular disease), hepatic, renal, gastroenterologic, respiratory, endocrinologic, neurologic (other than AD), psychiatric, immunologic, cancer or hematologic disease and other conditions that, in the investigator's opinion, could interfere with the analyses of safety and efficacy in this study;
- Has a history of chronic alcohol or drug abuse/dependence as defined by the Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition (DSM-IV) within the past 5 years.
- Presence of severe positive neuropsychiatric symptoms.
- The patient suffers from mental retardation, organic mental disorders, or mental disorders due to a general medical condition
- History or presence of any medical condition or disease which, in the opinion of the Investigator, may place the subject at unacceptable risk for study participation.
- The patient is, in the investigator's opinion, unlikely to comply with the protocol or is unsuitable for any reason
- Legal incapacity

2.4.3 Safety Issues
Ensuring the safety of the RAMCIP robot users is a major priority for the RAMCIP project. Safety issues shall be treated in the RAMCIP project trials within two basic dimensions.
The first concerns the project’s aim to research and develop a service robot that will be inherently safe, by both appropriate H/W design and S/W algorithms. During the design and development of the RAMCIP robot, the project’s research
efforts should follow closely the standardization efforts related to safety in the service robots domain. In this scope, of major importance is the ISO 13482:2014 standardization effort (Robots and robotic devices -- Safety requirements for personal care robots). ISO 13482 is an international standard that provides guidance to manufacturers and suppliers of personal care robots to ensure that they are designed, built and used safely. It’s the first internationally-recognized safety standard to cover the emerging field of personal robotics. Further details over how safety issues are planned to be handled from the more technical perspective, during the design and development of the RAMCIP robot, are to be provided in the deliverable D2.2.

The second dimension concerns the conduction of the project’s pilot trials in a way that will maximize user safety; in the pilot trials of the RAMCIP project, interaction between the human participants and the RAMCIP robot shall be established in a safe way. To this end, the pilot experiments of the RAMCIP project have been designated to be supervised by appropriate personnel, who shall ensure maximum user safety (see also Section 2.4.2 above and the Ethics Manual of the RAMCIP project at Annex I). Moreover, it should be noted that the project’s Ethics Advisory Board (see Section 3) will carefully check the specific, detailed protocols of the RAMCIP pilot trials, prior to their submission to the local ethical committees for their final ethical approval, over safety issues that may be involved in the planned trials.

### 2.4.4 Gender Issues

The aspect of gender issues will be addressed in two ways in the RAMCIP project, concerning a) researchers and b) user involvement.

**a) Involvement of researchers.** Gender composure in the professionals related with the studies will be considered. Despite the common knowledge that in Informatics and Engineering Degrees more men than women are involved, it is also known that in Psychological and Social Sciences more females are implicated. Partners’ and professionals’ background in RAMCIP in somehow balanced since there are professionals of both genders equally involved in Informatics, Engineering, Social Sciences, and Medicine.

**b) User involvement.** During the recruitment of potential users for the project, men and women will be involved at the comparable level. RAMCIP members will specifically focus on the issue how to implement the robot device so that all people may work equally well with the suggested technology, regardless of their gender. While conducting the studies, researchers will try to observe potential differences (if any) in human interaction behaviour as an aspect of gender, age or disability that might have an influence on the methodology and design of the robotic device. These issues and potential differences should be taken into account during experimental design and cohort recruitment in the two project pilot sites, it will be ensured that gender dependent differences will be capable to be assessed during the data analysis stage.

### 3. The RAMCIP Ethics Advisory Board

An Ethics Advisory Board (EAB) has been set up by LUM and ACE partners of the RAMCIP project. The board will supervise and regularly check all project activities performed within RAMCIP on their agreement with ethical regulations and principles. The Ethics Advisory Board will especially assess the methodologies and attitudes applied in the experiment in order to guarantee that all ethical principles will be applied. The Ethical Protocol will include the following methods and attitudes.
All project partners are obliged to report any ethical issue to the attention of the Ethics Advisory Board for an ethical analysis. Every questionable ethical case will be considered according to proper regulations. The main responsibilities of the Ethics Advisory Board can be summarized as follows:

- Confirmation of test plans
- Legitimacy of the experiment and the evaluation project and the assessment of the risk/benefit
- Enrolment of volunteers and method of obtaining informed consent
- The supervision under methodologies and approaches applied in the project
- Participant’s security and safety
- Protection and privacy of gathered data
- Informed consent of the end-user
- Proper Ethics Committees request
- The assurance that any danger of harm to volunteers during their interaction with a robot device is eliminated.
- Suitability of the physician(s) or researchers(s) and facilities

The basis for the RAMCIP Ethical Policy lies in the guidelines of professional committees in the field. It is the responsibility of the RAMCIP Consortium to guarantee that those requirements will be distributed to all involved partners and will be suitably adopted. To this end, the RAMCIP internal Ethical Advisory Board has been created.

The Ethical Advisory Board of the RAMCIP project was set up on Month 3 and involves a centralized service providing continuous advice on ethical and data protection issues that may appear throughout the project lifetime. The RAMCIP Ethical Advisory Board is also in charge of introducing and managing the ethical and legal issues referring to all processes in the project, giving an assurance that each partner provides the obligatory participation and its code of conduct towards the Pilot participants. All techniques and adequate recruitment protocols will be validated first by the RAMCIP Ethical Advisory Board. Special attention will be paid to the preparation and the initiation of the Pilots. Each crucial legal and ethical issue will be addressed to eliminate undesired effects.

The structure and role of the RAMCIP EAB is further clarified in what follows.

### 3.1 Structure of the Ethics Advisory Board

All members of the Ethics Advisory Board of RAMCIP Consortium are trained doctors and researchers having to deal with the legal aspects concerning research on humans in their daily lives. They are experienced scientists who are facing ethical and legal aspects at every step of their professional work. They are also being constantly trained in this field, both as doctors, as well as researchers.

The part of the RAMCIP project are two pilot trials sites - highly specialized centers, dealing with patients with dementia, where the checks on the RAMCIP robot will be performed and the data on end users will be collected. Thus, it was a natural decision to choose Ethics Advisory Board members from these institutions.
Realizing the importance of ethical and legal issues that may occur during the conduction of such specialized studies using the highest technology, data recording and monitoring of patients, both in their natural environment (home environment - ACE) as well as simulated one (Neurology Department of LUM), on the first meeting of the RAMCIP Consortium it was agreed unanimously that the function of the ethical guardians of pilot should perform the most experienced investigators - the heads of these centers. They are respectively: prof. Konrad Rejdak PhD, MD and Ms Merce Boada Rovine PhD, MD. The leaders asked their most experienced doctors about cooperation, one from each center – Dorota Szczesniak-Stanczyk PhD, MD and Carla Abdelnour MD. In addition, during the first meeting of RAMCIP, representatives of the pilot sites were obligated, at the express request of the main coordinator, to find in their own countries specialists dealing with ethical issues in research involving patients. They could not, however, be linked to institutions in which the tests are carried out. It ensures maximum objectivity of their opinions and decisions, regarding the sphere of legal and ethical project. The main responsibilities of EAB were named at the very beginning of the project.

### 3.2 Role of the RAMCIP Ethics Advisory Board

**Opinion of EAB given on request:**

If the consortium partners ask for an opinion on planned actions or documents and they address EAB, EAB is obliged to convene a teleconference which shall involve at least two members of the EAB. The mentioned members shall send response to the reported problem within one week. The answer should be drafted and approved by at least two members of the EAB. The answer should be in writing and shall contain EAB suggestion of solutions to reported problems.
Continuous monitoring of project activities:

RAMCIP consortium is convening meetings of all partners every three months to discuss current activities associated with project plan and cycle. These meetings involve delegations of all partners. During the meeting, in short presentations, representatives inform other members of the consortium about the work done on the project and the planned activities for the following months. The RAMCIP consortium conferences which take place every three months shall involve at least one member of the EAB. This person is obliged to evaluate presented activities of each partner as to their compliance with applicable international law and ethical standards.

The member of the EAB participating in recurrent meeting of RAMCIP consortium shall, within one week after the meeting, write a short report/coverage on legal or ethical issues that arise during particular presentations. It is recommended to use a table containing the names of each presentation, a brief description of the discussed issues and the ethical or legal aspects directly related to the described subject. The template of a report table is shown below.

<table>
<thead>
<tr>
<th>No.</th>
<th>Presentation's name</th>
<th>Brief description of presentation</th>
<th>Ethical and legal aspects</th>
<th>Mitigation strategy</th>
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</thead>
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<td>2</td>
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The table above shall be sent to all members of EAB within one week after the recurrent meeting of RAMCIP Consortium. Within next two weeks, the members of the RAMCIP Consortium should hold teleconference between at least two members of the two pilot trials and the mentioned ethical issues should be discussed. If any ethical risks are identified, they should be reported immediately to the partner responsible for the WP and the strategy of mitigation should be implemented.

In order to help EAB members to identify any potential hazardous events that may occur during the project lifetime, it has been decided to prepare Annex IV - "Potential hazardous events concerning Ethical Issues".

In Annex IV of Ethics Manual, Potential Ethical Hazardous Events have been drafted based on the literature review and RAMCIP Project Partners' experience from the previous projects.

Potential Ethical Hazardous Events may be addressed as:

- observed in HRI (Human-Robot Interaction) potential hazardous events and
- as the general potential hazardous events concerning common ethical aspects.

The detailed analysis of the potentially hazardous events observed during HRI could be found in Annex VIII of the M12 Trials Protocol Draft. As well some of key aspects of potentially hazardous events from the ethical point of view may be found herein (Chapter 2 Ethical Issues).

The examples of the ethical events, as well as, means of their identification, evaluation of controllability level, and recommended mitigation strategy may be found in Annex IV as a table "Potential ethical risks".
In case of detecting the risk of an ethical nature, EAB members are obligated to immediately communicate with a representative of the leader responsible for WP in which the threat was recognized.

Identified risk of an ethical nature should be reviewed by at least two members of the EAB. After the analysis, the members should formulate suggestions for the use of actions helping to avoid danger. If possible, several solutions of the problem should be presented, so that the partner responsible for that task could choose the most convenient option.

Immediately, teleconference between a representative of the EAB and the person responsible for the task in which the mitigation of an ethical nature occurred should be convened. Proposed solutions should be presented and the chosen solution shall be implemented immediately.

**Figure 2. Overview of the RAMCIP EAB activities**

**Verification of deliverables:**
In cycle of preparation of each deliverable at least one member of the EAB should attend. This particular member should have an insight into the document from the very beginning of its establishment, so that any ethical problem could be solved immediately. In case of detecting any legal or ethical risk by the controller of EAB, he/she should immediately contact the author of deliverable. The detection of risks in the early stages of the project significantly improves the work on particular task and helps to avoid a snowball effect.

**Involvement of External Advisors:**
The qualified external experts aim to periodically supervise the activities of EAB. There was taken up a decision to ask for their opinion every year, on the overall control of the project and for checking the documents having to be presented to the Ethics Committee in Poland and Spain. Thus, the members of the EAB are...
committed to invite External Advisor every year and present the progress of the project and the emerging ethical aspects, at the same time asking for an opinion. Documents to be approved by the Ethics Committee must first be accepted by External Advisors.

3.3 Members of the Ethics Advisory Board.

Members of ACE:

1. Merce Boada Rovira, MD, PhD

Neurologist, born in Barcelona, Dr. Mercè Boada is founder and medical director of Fundació ACE. Institut Català de Neurociències Aplicades. Until 2013 she was responsible for Neurodegenerative Diseases Unit at the Neurology Service, University Hospital Vall d'Hebron, and Head of the research group "Alzheimer" at the Vall d'Hebron – Research Institute (VHIR), Barcelona, Spain.

Her activity is focused on the treatment of Alzheimer's disease and related dementias. Especially interested in research on the factors involved in the degenerative process of AD and vascular dementia; genome and phenome of common diseases; neuroimaging biomarkers for the diagnosis of prodromal AD, and design of new pharmacological and non-pharmacological treatments.

She is the co-director of «Documento Sitges» on the ability and rights to decision making in the process of dementia. She leads the Observatory on Cognitive Health, Autonomy and competence, «OBSCAC», since 2011.

She was the coordinator of the care model design for people with dementia within the public health system of Catalonia («Model d'atenció per les persones amb deteriorament cognitiu i demència de Catalunya») (1991), She has been Technical Secretary of the Psychogeriatric Council of Catalonia (1996-2001), president of the Pharmacological Treatment for Alzheimer's Disease Advisory Board (1996-2001), member of the Bioethics Committee of Catalonia, and member of the Ministry of Health of the Catalan Government Advisory Board.

She has served on the National Expert Group for the development of the «Standards and recommendations for quality and safety in health centers and services» of the Spanish Ministry of Health, Social Policy and Equality (2011).

He has published more than 125 articles with an impact factor 128,58 (h index, 27) in 2014, 25 book chapters and 12 books of medical outreach.

Winner of the Award for Professional Excellence by the Medical Council of Catalonia (2008) and the Josep Trueta Medal for health merit, by the Generalitat de Catalunya (2012)

2. Carla Abdelnour MD

Graduated from Medical School of the Central University of Venezuela in 2007 and obtained the Neurologist Degree at the University Hospital “Príncipe de Asturias” in Madrid (Spain) in 2014. She have published 8 peer-reviewed book chapters in general neurology, and presented 11 oral communications (in national congresses) and 20 posters (4 in international and 16 national congresses) during her residency. Carla Abdelnour has special interest in vascular neurology (she has done an Observership from January to March 2014 at the Stroke Institute, University of Pittsburgh Medical Center in Pennsylvania, USA) and
neurodegenerative disorders, in particular Alzheimer’s Disease and Parkinson Disease. Currently, she is a consultant neurologist and subinvestigator of research studies at Fundació ACE, Barcelona Alzheimer and Research Center in Spain: Phase I pilot study, randomized, controlled with placebo, with parallel groups, double blind and unicentric, destined to evaluate the tolerability and safety of the subcutaneous administration of two doses of ABvac40 to patients with early or moderate Alzheimer’s Disease and A Double-blind Placebo-Controlled Randomized, 4 Week, Multiple-Dose, Proof-of-Mechanism Study in Subjects with Early Alzheimer’s Disease Investigating the Effects of JNJ-54861911 on Aβ Processing in CSF and Plasma.

**Members of LUM:**

3. **Prof. Konrad Rejdak PhD MD**
   
   Graduated from the Medical University of Lublin (Poland) in 1996. He was awarded a PhD in medical sciences from the Medical University of Lublin having worked on endogenous neuroprotection mechanisms induced by different brain insults in neurological diseases. In 2009 defended his habilitation dissertation dedicated to neurodegenerative processes in relation to inflammatory mechanisms in multiple sclerosis as compared to neurodegenerative diseases. Prof. Konrad Rejdak trained clinical neurology in Lublin (Poland) and had clinical attachments in Brescia (Italy) and London (UK). His research and clinical interests include neurodegenerative diseases, epilepsy and multiple sclerosis. Other interests include biomarker discovery, for studying pathogenesis of neurodegeneration. He was trained in clinical biochemistry at the Department of Neuroinflammation, Institute of Neurology, UCL in London (UK) during his Marie Curie Fellowship awarded from EU. He performed several projects relating to the markers of inflammatory and neurodegenerative processes in the course of neurological diseases, publishing the results in international peer-reviewed journals (MedLine database includes 50 records with cumulative impact factor of 135 points, HI=14). He presented over 150 abstracts at national and international meetings and is a member of several national and international scientific societies. Currently, prof. Konrad Rejdak is a consultant neurologists and head of the Department of Neurology, Medical University of Lublin and associate professor at the Department of Experimental Pharmacology, Medical Research Centre, Polish Academy of Sciences in Warsaw (Poland).

4. **Dorota Szczesniak-Stanczyk PhD MD**
   
   She graduated from the Medical University of Lublin (Poland) in in 1998. She is a physician, internal medicine specialist with scientific background in the area of cardiology, (especially novel cardiac pacing and cardiac monitoring techniques) and medical genetics (PhD thesis in 2006). Recently she cooperates with industry in the area of medical applications of robotic systems. Dr. Szczesniak-Stanczyk is an author of the idea of the ReMeDi project (7PR) and currently she is responsible for the medical aspects of the ReMeDi project. She has also 3 years’ experience in the project management in the sector of new drugs and medical devices development as a clinical safety specialist.

**Additionally, External Advisor, one for each team (country):**
5. **Prof. Xavier Carne i Cadellas MD PhD - Spain**

Specialist in Internal Medicine and Clinical Pharmacology. He is currently head of the Department of Clinical Pharmacology, Clinical Hospital of Barcelona. He is Professor of Pharmacology, Department of Pathology, Pharmacology and Microbiology, University of Barcelona. He is a member and Spanish representative in Europe of the Executive Committee of the European Clinical Research Infrastructures Network, advisor to the General Directorate of Pharmacy and Health Products and chairman of the Evaluation Committee for Medicinal Products for Human Use of the Spanish Agency for Medicines and Health Products. He has published original articles in medical journals indexed and book chapters on clinical pharmacology, clinical trials, research methodology and therapeutic.

6. **Prof. Marcin Olajossy PhD MD – Poland**

(born in 1946 in Lublin, Poland). Studied at Medical University of Lublin. Straight after graduating in 1969 with high honors he starts working in Psychiatric Clinic of Medical University in Lublin. During his carrier in the Clinic he has gained first and second degree of specialization in Psychiatry, as well as was awarded a Ph.D. in medical science in 1978. For several years he had a position of Regional Psychiatric Consultant in regions of Lublin and Zamosc. Between 1992-2000 he was lecturer at the Faculty of Psychology UMCS. From 1992 till now he has been collaborating with Catholic University in Lublin, where he lectures psychopathology and pastoral medicine. He has published range of original articles in polish medical journals. He is an author of chapters in medical books regarding psychopathology, schizophrenia, pastoral medicine and many others. He is currently in charge of Lublin Psychiatric Society and he is the Head of The Department and the Second Department of Psychiatry and Psychiatric Rehabilitation of Medical University of Lubin.

In a nutshell, the core function of the RAMCIP Ethical Advisory Board is to provide at any time all the information that one may require, and at the same time is responsible for the arrangement and the initiation of the pilots. Although the aim is to gain the best possible results, it should be always with respect to the human factor, the rights and liberties that are established by European and National Laws. The Ethics Advisory Board aims to guarantee that all activities performed throughout the RAMCIP project are in accordance with the ethical regulations and principles as addressed in current project. The Board will also regularly review the Ethics Protocol and make improvements when necessary.

### 4. Ethics Risk Management

After careful analysis with collaboration with the project partners we have identified the following ethical issues that withhold main importance in the context of the RAMCIP project. The Ethics Advisory Board of RAMCIP will carefully oversee all relevant project activities throughout the project duration, so as to ensure that these risks are minimized. In order to define the risks, all members of the consortium were politely asked to identify ethical risks associated with their domain, using their knowledge and experience on the possible dangers that may arise in connection with work on Work Packages.

<table>
<thead>
<tr>
<th>No.</th>
<th>Risk Description</th>
<th>Risk exposure level</th>
<th>Risk Mitigation</th>
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|   | Loss of Privacy Control. Participants will be monitored and their personal data will be gathered. | Medium | All personal data gathered from participants of the RAMCIP data collection experiments will be securely stored and restricted access will be provided to project partners only when necessary for the project research purposes. All source materials or data will be eradicated after that, if this is not against the law of the country in which the information was gathered, stored and analysed.
Regarding user monitoring through computer vision, images taken from the camera of the final RAMCIP system will be processed and immediately discarded. Only absolutely necessary information for the system's operation in the form of features will be kept locally on the robot and will be deleted as soon as they are not necessary. |
|   | Difficulty in providing security to shared Personal Data | Medium | The project will focus on giving an assurance of confidentiality and for incorporating PET technologies to ensure safeguarding from data breaches. The consortium has the ability and the experience to deal with the security mechanisms delivery, if needed. |
|   | Storage and Process of personal Data. Confidentiality | Medium | Both the pilot and technical partners of RAMCIP possess the knowledge and the background from similar past and on-going research projects, towards indicating the necessary ethical requirements that should be adopted during the establishment of the project pilots. Local ethical committees will be given detailed information toward obtaining an official approval for the execution of the pilot trials. |
|   | Lack of Transparency | Medium | The Ethical Advisory Board will give the necessary feedback in order to both minimize this risk as well any other similar danger that may occur during the project duration. Furthermore, during the pilot trials the local ethical committees will be informed about the personal data gathered as part of the research study and the desired documents will be prepared by the consortium pilot members in order to get an ethical acceptance. |
|   | Delegation of | Medium | The project involves a dedicated task |
| Control Privacy. Incidental Findings | of WP2 in order to address local and European law and continuously monitor project activities on this basis. In this context, all the pilot trials will be carried out according to the relevant legislation and relevant data protection authorities will be informed on time. Moreover, in case of the Polish and Spanish pilot trials, the local ethical committees will be also informed and all necessary documents will be prepared for the pilot trials (e.g. informed consent, purpose of research, etc). The Ethical approvals from the committees will be also communicated to the EC. |
| Loss of data from home monitoring | Medium | Data security issues see point 1 of the table 7. Additionally the consortium partners do not intent to publish visual material from real home environments. During video recording it should be avoided to record widely known landmarks e.g. buildings, monuments of history visible through windows. |
| Improper use of IT Equipment | Medium | All technical partners have the proper knowledge to make the suitable establishment for the purposes of the pilots. Indicatively, CERTH has taken part in several National and European projects referring to integration of sensors for research purposes and their use in ethical accordance with National and European legislations. The RAMCIP Ethical Advisory Board will control pilot procedures ensuring the correct use of IT equipment. |

The RAMCIP Consortium decided on the selection of the methodology described below as a tool to facilitate the continuous monitoring, identification and management of potential ethical risks. This method is aimed at early detection, assigning categories and mitigation strategies for each potential ethical risk that may arise during the lifetime of the project. At an early stage of the project, which is ongoing, it is not possible to identify every kind of danger that may appear on the next project stages. However, the experience of the consortium partners in their work during previous projects allows to predict a substantial part of potential ethical risks that may arise at a later time. Early identification of ethical risks that may arise, can lead to either completely avoid them, or develop a strategy to mitigate the effects of their impact on the ethical security of consortium and all potential members of the project, as well as volunteers or end-users and their families.

**Risk Assessment** is treated as a main element in the experiment realm, particularly in projects that analyse modern and intelligent technological solutions. Researchers have to focus on a complicated and often inter-related mix...
since there are different possibilities and risks existing in every project. When possible risks are defined, they have to be allayed. Thus, a plan for unexpected situations must be made in order to diminish the possible delays or failures.

The definition of a risk says that it is an event that has a possibility of occurring and may have a negative influence on the experiment. There may be one or more causes of the risk, if it appears, and one or more consequences. In the same circumstances, a contingency plan is described as a set of activities to be done if any danger occurs.

It is important to emphasize the fact that Risk Assessment is a continuous procedure during the RAMCIP project and it will be present throughout its duration. It is also worth mentioning that it is impossible to completely diminish the potential of risk occurrence. Nevertheless, working in accordance with the contingency plan may suppress the risk’s potential and prepare researchers for dealing with it to minimise its influence on the project. In this scope, this section focuses on analysing risks in the context of the RAMCIP ethical issues.

**Risk Management** concerns the identification, assessment and prioritisation of risks followed by coordinated and rational usage of resources to monitor, control and mitigate the probability and impact of unfortunate events. Ethical issues as crucial for RAMCIP project need to be given a multivariate analysis in order to obtain a clear view on the potential malicious risks, their recognition and mitigation of the potential threats.

### 4.1 Risk Analysis

The Risk Analysis methodology adopted herein consists of three main levels:

- Risk Identification: recognition of ethical issues that may be threatened with incompatibility with main law and ethical guidelines principles
- Risk Evaluation: measuring the potential impact of the risk on the outcome of the project in qualitative and quantitative indicators
- Risk Categorization: arranging potential risks into classes, in order to designate the most important ones that will demand for immediate action

### 4.1.1 Risk Control

The Risk Control methodology also needs to be conducted in three steps:

- Risk Planning: indicate special project units and chart plan to keep from the impact of risk
- Risk Resolution: creating strategies in order to minimize the probability of every risk
- Risk Monitoring: define project tools that will monitor for potential ethical risks during the project lifetime

### 4.1.2 Risk Identification

To identify the nature and levels of risks in the field of ethics, consortium members and especially the Ethical Advisory Board members have to focus on the main threats included in the tasks of each WP.

They should analyse if:

- The actions taken in every WP are applicable to national and European law
- The tools used to achieve the goals of each WP are legal under EU law and do not violate any human rights.
- The data concerning project participants is properly stored and processed
- The participants are taking part in the project freely and willingly

4.1.3 **Risk Evaluation**

Considering and conducting the identification of ethical risks in projects is very important toward ensuring an ethical result. (a) Suspecting and early detection of the likelihood of any incidence and also the (b) possible effect of any looming danger which may occur as the project develops and eventually (c) getting closer to the stages of producing results, could be said to be the usual and most popularly known points when it comes to aspects of risk evaluation. An instant challenge of the magnitude of the likelihood and incidences is generated when applying the above mentioned capability concerning risk analysis. Generally, it is problematic to apply an advanced mathematical equation to completely solve the total and accurate possibility of risk exposure of a particular deliverable for most known projects. In what follows, in order to assess the degree of risk and get a considerable result, the RAMCIP consortium will follow the notation “Probability level” and “Impact level” that seems to be more relevant in the case of our project.

Herein, both the "Probability level” and “Impact level” as warning symbols are viewed to possess more resilience and a degree of freedom in the assessment of risks, which is necessary for a complex three year research project like RAMCIP; for which dangers associated with projects and urgently need costs are simply difficult to incorporate.

Therefore, both the “Probability Levels” and “Impact levels” of possible ethical risks for the project are represented in the tables below:

### Table 4 Risk Impact Description and Value

<table>
<thead>
<tr>
<th>IMPACT LEVEL</th>
<th>VALUE</th>
<th>DESCRIPTION</th>
</tr>
</thead>
<tbody>
<tr>
<td>HIGH</td>
<td>3</td>
<td>Significant impact on the project’s strategy or operational activities</td>
</tr>
<tr>
<td>MEDIUM</td>
<td>2</td>
<td>Moderate impact on the project’s strategy or operational activities</td>
</tr>
<tr>
<td>LOW</td>
<td>1</td>
<td>Low impact on the project’s strategy or operational activities</td>
</tr>
</tbody>
</table>

### Table 5 Probability of Risk Occurrence

<table>
<thead>
<tr>
<th>PROBABILITY LEVEL</th>
<th>VALUE DESCRIPTION</th>
<th>POSSIBLE INDICATORS</th>
</tr>
</thead>
<tbody>
<tr>
<td>HIGH (PROBABLE)</td>
<td>VALUE 3: VERY LIKELY TO OCCUR</td>
<td>Potential of it occurring several time within the project time period</td>
</tr>
<tr>
<td>MEDIUM (PROBABLE)</td>
<td>VALUE 2: LIKELY TO OCCUR</td>
<td>Could occur once or more than once within the project time period</td>
</tr>
<tr>
<td>LOW (PROBABLE)</td>
<td>VALUE 1: NOT LIKELY TO</td>
<td>Unlikely to occur during project time period</td>
</tr>
</tbody>
</table>
Starting from value 1 to 3, “Probability level” and “Impact level” can be predicted, demonstrating and expressing the three of the major and possibly dangerous cases. In order for a straightforward and easy understanding, a proper layout of the risk should be presented and for the adequate support to the comprehensive analysis backing the translated three scale segment of the risk scenarios.

The importance and worthiness of the work at hand, and its vulnerability to both internal and external project risks forms a further significant factor for the risk evaluation analysis; for instance, a task that is subject only to internal threats and possesses a low level of dependencies from the results of other ongoing tasks, is expected to possess low level value. The assessment shall acknowledge that not all functions have the same importance in terms of worthiness despite the fact that it is well known that all foreseen tasks could be valid for the implementation of a project like RAMCIP.

### 4.2 Risk Categorization

Risk classification which is also known as risk categorization or risk grouping, is one of the most influential factors of the risk evaluation procedure. Risk categorization makes it far much easier to figure out in timely manner the level of risk exposure of every project function, through evaluation and manipulation of the arithmetic outcome from the risk evaluation procedure, which makes the know-how of the relevance of the risk involved possible:

\[
\text{Risk exposure level} = \text{Probability level} \times \text{Impact Level}
\]

Importance of a Risk = Value of task \( \times \) Risk Exposure Level

In order to assess and rank classified risks, the RAMCIP consortium will take into scrutinize the sensitivity level as regards the arithmetic manipulation of the exposure level:

- 1-2 → Low Risk
- 3-5 → Medium Risk
- 6-9 → High Risk

<table>
<thead>
<tr>
<th>Table 6. Risk Category Matrix</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Probability</strong></td>
</tr>
<tr>
<td><strong>Remote (1)</strong></td>
</tr>
<tr>
<td><strong>Possible (2)</strong></td>
</tr>
<tr>
<td><strong>Probable (3)</strong></td>
</tr>
</tbody>
</table>

The three definite exposure levels could be seen in the conclusion of the 3 x 3 Risk Categorization matrix table above, with the green boxes representing “low risk” exposure level, the yellow boxes showing a “medium risk” exposure level and the red boxes indicating the presence of an “eminent risk” exposure level that calls for strategies for risk planning to be subsequently established.
4.3 Risk Planning

The establishment of a Risk Control methodology needs to start with Risk Planning. Risk Planning illustrates the process of outlining and working under a stable plan that exploits and develops the results of the risk analysis methodology. All the stages of the project must be carried out by taking into account the risk plan, which should be properly adopted and followed throughout the project lifecycle.

The plan predicts:
- Techniques of risk determination
- Techniques of risk controlling
- Continuous updates of the plan in accordance to current expected or unexpected progress
- The establishment of specific instructions and individual obligations regarding the management of the plan

The actions performed throughout the Risk Control are used to work with the defined layer of available information that has emerged from the Risk Analysis process. Particularly, the Risk Control methodology is responsible to introduce all consistent information in compliance with the characterization of the risk, the conditions that influence its appearance, methods of prompt levelling of the risk, as well as boundaries of duties of the project units and executive responsible for monitoring project risks; in our case this corresponds to the RAMCIP Ethical Advisory Board.

Finally, the process called Risk Categorization is responsible to recognize the weight and the importance of a single risk as it enters the risk plan.

4.4 Risk Resolution

In order to resolve the identified risks, numerous methods are suggested:
- Prevent the risk by isolating its probable connection with project tasks
- Try to define risks on time, accept the probability of adversity loss with fast transition to treatment of risk impact
- Diminish, on time, the possibility of risk occurrence by getting rid of the factors which can start the chain of event
- Make frequent updates of project strategy to easily detect risk and finally receive profit from risk situation if possible

Despite the existence of solid Risk Resolution methodology, we cannot treat the project as risk occurrence free since risk with probable severe effect must be further analysed and closely examined for the purpose of minimizing their consequences.

4.5 Risk Monitoring

Risk Monitoring is a very useful method of obtaining the definition of the high level risks under constant diligence. In order to achieve a proper risk monitoring process, repetitive updates of the entire risk management procedure are necessary. Additionally, most prominent risks and their development must be reported on time.

The achievement of what was listed above may be successful if each risk will maintain the following information:
- Risk characterization
- Progress in treatment
- Probable risk adjustment and development
- Current position in the risk categorization hierarchy
- Previous position in the risk categorization hierarchy
The effectiveness of risk monitoring depends also on a reporting and review structure that guarantees successful risk characterization and estimation and ensures suitable management and treatment. What should be also taken under consideration is the regular examination of adopted policy and applied standards. Additionally, the method of constant improvement should be used.

In the following, Table 7 first outlines the tasks of the RAMCIP project and Table 8 summarizes so far identified ethical issues that are involved in the different project WPs.

### Table 7 Workpackages of the RAMCIP Work Plan

<table>
<thead>
<tr>
<th>WP NUMBER</th>
<th>WP TITLE</th>
<th>LEAD BENEFICIARY</th>
</tr>
</thead>
<tbody>
<tr>
<td>WP 1</td>
<td>Project Management</td>
<td>CERTH</td>
</tr>
<tr>
<td>WP 2</td>
<td>User Centric Requirements and Definition of the RAMCIP System</td>
<td>LUM</td>
</tr>
<tr>
<td>WP 3</td>
<td>Monitoring and Modelling Human Activity at Home</td>
<td>CERTH</td>
</tr>
<tr>
<td>WP 4</td>
<td>Human Robot Communication</td>
<td>FORTH</td>
</tr>
<tr>
<td>WP 5</td>
<td>Advanced Grasping and Manipulation</td>
<td>CERTH</td>
</tr>
<tr>
<td>WP 6</td>
<td>Physical Human Robot Interaction</td>
<td>TUM</td>
</tr>
<tr>
<td>WP 7</td>
<td>Platform Development and Integration</td>
<td>ACCREA</td>
</tr>
<tr>
<td>WP 8</td>
<td>Assessment of the RAMCIP system</td>
<td>LUM</td>
</tr>
<tr>
<td>WP 9</td>
<td>Dissemination and Exploitation</td>
<td>SHADOW</td>
</tr>
</tbody>
</table>

Ethical risks of the RAMCIP project will be assessed throughout the project’s duration by the RAMCIP Ethics Advisory Board, on the basis of the methodology described above, in agreement with the overall RAMCIP consortium.

After careful analysis, discussion and evaluation of the degree of risks, a potential risk exposure level is attributed to each of the risks. Being aware of the consequences of ethical risks, consortium and WP leaders, after consultation with members of the Ethical Advisory Board, identify solutions to mitigate any ethical risks. The foundations for this process have already been set through the preliminary analysis of potential ethical risks that are involved in the RAMCIP project, the outcome of which has been presented in the beginning of the present chapter. This preliminary analysis provides the present deliverable and the project’s Ethics Advisory Board with a stating point over the respective risk assessment and management process that will remain active throughout the project’s duration. Nevertheless, it should also noted that due to the early stage of the project, neither the present analysis can be considered as complete, nor the list of the potential ethical risks of the RAMCIP project, as it is expected that further ethical risks may arise and be identified in the project’s course.

In this scope, not only should the Ethics Advisory Board perform a continuous monitoring and assessment of project activities related to the so far identified ethical risks, but each member of the consortium is also required to report...
emerging ethical risks to the assessment of Ethics Advisory Board and to the cooperative analysis of possible ways of its mitigation. The members of the EAB should also continuously monitor tasks relevant to ethical issues involving human data collection, human monitoring and informed consent issues. Work packages that should be closely monitored by EAB and their relevance to ethical issues are presented in Table 8 below.

Table 8 Work packages potentially involving data collection from human participants and their relevance to ethical issues

<table>
<thead>
<tr>
<th>Work Package</th>
<th>Description of WP</th>
<th>Relevance to Ethical Issues</th>
</tr>
</thead>
<tbody>
<tr>
<td>WP 2 User Centric Requirements and Definition of the RAMCIP System</td>
<td>Detailed analysis of users' expectations and their potential capabilities of cooperation with RAMCIP; specification of user requirements and use cases</td>
<td>- user’s data protection and participants data security</td>
</tr>
<tr>
<td>WP 3 Monitoring and Modelling Human Activity at Home</td>
<td>Providing the robot with the capability to sense the home environment and human activity within it and intervene when necessary</td>
<td>- security of data collected from sensors, computer vision data, respect of the home and family life privacy</td>
</tr>
<tr>
<td>WP 4 Human Robot Communication</td>
<td>Research and development of mechanisms enabling communication between humans and the RAMCIP system</td>
<td>- protection of information gathered by the robotic system</td>
</tr>
<tr>
<td>WP 6 Physical Human Robot Interaction</td>
<td>Developing of mechanisms for introducing safety in the RAMCIP robot under intentional and unintentional physical contacts with human participants</td>
<td>- protection of visual data of participants collected from the sensors during relevant data collection experiments; safety of participants should be ensured</td>
</tr>
<tr>
<td>WP 8 Assessment of the RAMCIP system</td>
<td>System evaluation methodology and preliminary tests</td>
<td>- protection of sensitive medical data of participants, data collected by the robot sensors, respect of the home and family life privacy</td>
</tr>
</tbody>
</table>

To conclude with, based on our preliminary analysis of the ethical risks involved in the RAMCIP project, RAMCIP poses some ethical risks, which are however controllable through appropriate mitigation strategies; this along with the constant monitoring of project ethical issues by the RAMCIP Ethics Advisory Board, can be considered to bring RAMCIP at a low-risk level concerning ethical issues.
5. Conclusions

The current document has presented the ethical scope of RAMCIP, as well as the strategy deployed for identification and continuous monitoring of the potential ethical risks that may occur during the development of the project. Furthermore, mitigation plans have been proposed in order to avoid possible negative risk impacts.

At the first part of the deliverable, the ethical framework of the RAMCIP project has been analysed, considering that RAMCIP is a research project dealing with MCI elder patients, including monitoring of home environments, private areas, whole body images and data collection. The ethical scope has received significant consideration from the very beginning of the RAMCIP project, and as the project unfolds and evolves it will be one of the aspects that will guide all the procedures. The ethical framework of the RAMCIP project, as analysed in the present deliverable, will be given due attention and will be carefully treated throughout the lifecycle of the project, toward ensuring that ethical risks will be appropriately addressed.

With respect to the European laws for Human Rights and the National laws for Ethics, the RAMCIP project introduces innovative ideas proposing new technologies in the scope of service robots for assisted living applications. The proposed robot shall be evaluated in the project pilot trials, whereas a series of data collection trials are foreseen in the project for the research and evaluation of S/W algorithms and methods; clearly, a series of project trials will involve data collection from human participants.

In this scope, an Ethical Advisory Board has been established in order to procure necessary information to any concerned party, to observe the compliance of the RAMCIP project with the documented ethical policy, and to monitor the preparation and realization of the pilots. Issues such as privacy control, data management, transparency and abnormal occupant behaviour are seriously taken into consideration. Before the establishment of the ethical guidelines ended, an “Ethics Manual” (see Annex I) has been delivered in the scope of WP2, in an effort to provide RAMCIP researchers with a concise framework of a series of basic guidelines that should be followed when designing trials of the RAMCIP project, when establishing them and when processing data collected from human participants in those. This is going to be regularly updated throughout the project based on new ethical questions or complications that may occur. The eventual version of the Ethics Manual will contain all the necessary information and guidelines for the issues addressed by the overall RAMCIP workplan.
References

[1] RAMCIP Grant Agreement Annex I – “Description of Action” (DoA)
[2] ETHICAL- Project co-funded by the EUROPEAN Commission under FP7 (D1.8 Quality and Risk Management Guide)
[8] Act on 5 December 1996 on the professions of doctor and dentist
[10] Subject Insurance during pivotal clinical trials. Ley 29/2006, de 26 de julio, de garantías y uso racional de los medicamentos y productos sanitarios
Annex I: Ethics Manual

PHC-19-2014: Advancing active and healthy ageing with ICT: service robotics within assisted living environments

Project Title:
Robotic Assistant for MCI Patients at home

RAMCIP
Grant Agreement No: 643433
Research and Innovation Action (RIA)

Ethics Manual

<table>
<thead>
<tr>
<th>Title</th>
<th>Ethics Manual of the RAMCIP project</th>
</tr>
</thead>
<tbody>
<tr>
<td>Authors</td>
<td>RAMCIP Ethics Advisory Board</td>
</tr>
<tr>
<td>Status:</td>
<td>Completed</td>
</tr>
<tr>
<td>Distribution:</td>
<td>All Partners</td>
</tr>
</tbody>
</table>
1. Introduction
RAMCIP aims to research and develop a service robot for elderly people with Mild Cognitive Impairments and at early dementia stages. To this end, existing technologies from the robotics community will be adopted and fused with further ones developed within the project, within user-centred design activities and practical validation, with the aim to create a step-change in robotics for assisted living.

The partners involved in the RAMCIP project range from experienced medical technologists through to SMEs developing robotics solutions. They have come together with the common goal of enabling a new generation of assistive technology, drawing on both their extensive experience and the enabling effects of European support.

More specifically, the RAMCIP project aims to research and develop a service robot capable to provide proactive and discreet domestic assistance to elderly with MCI and at early stages of Alzheimer’s Disease. During the project’s duration, data collection experiments involving human participation are foreseen; in the project’s pilot trials the final RAMCIP robot shall be evaluated.

2. Scope of the Ethics Manual
The present Ethics Manual has been developed by the RAMCIP Ethics Advisory Board in relation to the creation and circulation of the overall code of ethics that requires the proper review and scrutiny during the Polish and Spanish pilot trials, where the end-users will be engaged to interact with the RAMCIP robot and collection of data will take place, to enable the final evaluation of the RAMCIP robot. Moreover, the present Ethics Manual can also facilitate researchers of the RAMCIP project who will design further data collection experiments oriented towards the evaluation of specific algorithms (e.g. human activity tracking) that will be researched and developed in the context of the project’s further Workpackages (e.g. WP3, WP6).

A constant update of this manual shall take place throughout the project’s life-cycle, depending on the newly determined ethical challenges or threats that may arise and further specifications on the data collection procedures that will be involved in the project and the datasets that will be collected. The conclusive version of the Ethics Manual will contain more comprehensive and detailed information as well as guidelines concerning all topics in relation to RAMCIP framework.

The motive of this document first and foremost, is for the project researchers and overall staff participating in the pilots’ preparation and realization to be aware of ethical issues that are related to the project trials, so as to be facilitated in developing trial protocols that adhere to ethical guidelines and better suppress ethical risks, already in the initial phase of trials design, before the submission of the trials plan to the RAMCIP Ethical Advisory Board and subsequently to the local Ethics Committee of the trial site for the final protocol approval. Furthermore, the manual is aimed at all the people that are a part of the project, including researchers working on WPs that involve individual data collection experiments and processing of personal data, as well as the end-users and their families, who are viewed as the actual participants in the pilots and may require more details about the guidelines approved for and by the project.
3. Pilot Trials at LUM Premises in Poland and Real Home Environment of End-Users in Spain

A standard Pilot Evaluation procedure is planned for the RAMCIP project’s outcomes to be checked, analysed and fine-tuned as a whole. First of all, the RAMCIP Consortium plans to test the RAMCIP robot assistant in a reality-simulated environment in order to provide maximum safety for the user and efficiency of the robot actions. The Pilot trials will involve observation of the Human-Robot interaction in a specially prepared room at the Neurology Ward of LUM equipped with everyday appliances. The room will be adapted to the RAMCIP objectives and normal everyday appliances (such as kettle, wardrobe, sink) will be available to the participants. Moreover, the pilot trials of the RAMCIP robot will involve also controlled sessions of RAMCIP assistance applications that will be held at real homes of end users, under however the supervision of a medical expert from the RAMCIP consortium, who will ensure the safety of the user, as well as the robot.

In order to provide the highest level of security and enable the RAMCIP consortium to collect human behavioural data prior to the development of the final RAMCIP robot, for the purposes of early evaluation of the human behavioural monitoring methods that will be researched and developed in WP3, a separate user activity monitoring system will be installed at target users’ living environment (e.g. an adapted room of LUM) for long periods of days, which may not utilize a robotic platform, but could be based on strategically placed sensors (e.g. computer vision ones, such as Kinect). Special care will be put on adequately covering all potential issues of project trials related to privacy, duty of care and appropriate supervision/presence of a medical expert.

4. Monitoring and Control Infrastructures

A variety of sensors may be needed to be deployed in different positions for the need of the RAMCIP trials realization (e.g. strategically located computer vision sensors in the case of the preliminary experiments, prior to the development of the RAMCIP robot), to fulfil the project’s data collection purposes. Object recognition and tracking, 3D home environment modelling and monitoring methods will be tested in the laboratory and also in simulated/real home environments. Indicatively, research efforts will focus on SLAM and 3D object recognition/reconstruction methods based on the more privacy-preserving, depth modality, whereas the incorporation of also RGB video processing will as well be investigated, under consideration of user privacy needs. Apart from enabling the robot to robustly recognize the home environment and its objects, the proposed service robot should recognize and track humans as they move inside the environment. Gathering information from variety of sensors as a part of the research work has been made known to the local ethical committees of the pilot partners (LUM and ACE), with a documented provisional ethical approval agreement signed.

5. Legislation

The RAMCIP project in its entirety acknowledges the ethical rules of the EU, knowing that the pilot trials involving human participants would be held in Spain and Poland, by corresponding legislative laws of the nation. Precisely, the legislation that the RAMCIP framework has to comply to is:

2. Spanish Law:
• Ley 41/2002, de 14 de noviembre, básica reguladora de la autonomía del paciente y de derechos y obligaciones en materia de información y documentación clínica.
• Patient protection and informed consents. Ley 14/2007 de Investigación biomédica.
• Persona Data Protection. LEY ORGÁNICA 15/1999, de 13 de diciembre, de Protección de Datos de Carácter Personal. (http://www.boe.es/boe/dias/1999/12/14/pdfs/A43088-43099.pdf)
• Subject Insurance during pivotal clinical trials. Ley 29/2006, de 26 de julio, de garantías y uso racional de los medicamentos y productos sanitarios

3. Polish Law:
• The Polish Act on Personal Data Protection, 1997
• Regulation of the Minister of Health on May 2, 2012 on Good Clinical Practice (Journal of Laws of 2012, No. 489).
• Act on 5 December 1996 on the professions of doctor and dentist

6. Guidelines
This section provides a concise formulation of basic guidelines that can facilitate researchers of the RAMCIP consortium while designing and establishing the project's data collection trials, as well as when archiving and processing collected data, with emphasis on experiments that involve human participation and personal data collection and processing. More detailed information over the overall ethical framework of the RAMCIP project is provided in Section 2 of the present deliverable.

6.1. Personal Data
Personal Data must be:
• handled reasonably and in accordance to law;
• satisfactory, proper and not disproportionate in connection to the reasons for their collection and/or further processing/examination
• stored in a manner which allows the identification of data subjects to be made impossible, once this is no longer necessary for the purposes for which the data was initially collected and or for which they are further processed
• gathered solely for unique, precise and lawful purposes, and not further processed in any manner that is incompatible to those purposes. Further processing of information for research, statistical and historical reasons will not be regarded as incompatible provided that the authorities issue the needed protection
• accurate and when necessary, kept up to date, with all reasonable steps taken to ensure that any falsified information, data which is inaccurate or incomplete, in relation to the aim for which they have been gathered initially or for which they are further processed, are deleted or rectified.

6.2. Acquisition and storage of human related information
• No information gathered is permitted to be leaked, marketed or used for any other reasons different from the ones of the project at hand.
• No data should be gathered without the explicit written informed consent of the observed human subject.
• The trial supervisor should ensure that participants are informed with clarity about the procedure of the trial, the aims and operation of the system, the data collection and the data storage methodologies.

• No personal information should be centrally archived. It should be scrambled where possible and abstracted in a way that does not affect the experiment's target outcome.

• There should be no situation where personal data would be gathered in lieu of necessary ones given the current experiment's aims.

• Any shadow (ancillary) personal information obtained while running the experiment should be immediately repealed. Ancillary information of such nature should be decreased to the lowest possible form. Special consideration should be made to ensure adherence with the Council of Europe’s Recommendation R(87)15 on the processing of personal data for police purposes, Art. 2:

"The collection of data on individuals solely on the basis that they have a particular racial origin, particular religious convictions, sexual behaviour or political opinions or belong to a particular movements or organizations which are not proscribed by law should be prohibited. The collection of data concerning these factors may only be carried out it absolutely necessary for the purposes of a particular inquiry".

• An information minimization and reduction policy needs to be considered at all phases during the project and should also be monitored in terms of ethical/privacy issues by the project’s Ethical Advisory Board. This shall ensure that no data which is strictly necessary to the completion of the study at hand will be gathered.

• The burden for enrolled subjects should not be further to the one designated for participation in standard market research.

6.3. Collection of data from participants

The pilot supervisor or her/his official delegate is required to ensure that participants whose information is gathered have been provided at least with the following information:

• The purposes of the processing for which the information is being gathered,

• The name of the supervisor and other official delegates,

• Any additional information like:
  - Whether responses to questions should be given by the participant on an obligatory or voluntary basis and whether possible consequences may relate to failure to reply
  - The rights to amend as well as the right to access the information regarding them
  - The receiver or categories of receivers of the gathered information
  - In so far as such further information as necessary, in respect to the specific circumstances in which the data are collected, to guarantee an unbiased procedure and fair processing of the data

6.4. Rights of Participants

• By law, each and every participating member shall have the right to access their personal information, as well as the parameters that are extracted through processing of her/his data.
- Participating members have the right to quit the experiment at any point and withdraw their membership at any time, without any consequences. Such members have the right to check, update, modify and wipe out their information at any time.

Moreover each participant has the right to obtain the following from the trial supervisor and controller:

- The proper modification, annulment or restriction of information the processing of which does not comply with the provisions of this Manual, particularly due to incomplete or inaccurate nature of the data.
- Notification to other associates to whom information has been divulged of any possible modification, deletion or restriction, unless this proves impossible or involves a disproportionate effort.
- At reasonable intervals, without constraint and without excessive delay or expense:
  - Communication from the controller in a clear manner about the current data of her/his that is currently being processed and any possible reference to their origin
  - The know-how of the techniques used in automatic information processing as concerns her/him
  - Confirmation as to whether or not personal data concerning her/him are processed and the reason why it is processed, the categories of personal data concerned, and the receivers or groups of receivers to whom the personal information has been disclosed

The participant has the Right to Object:

- At any particular point in time on compelling legitimate grounds relating to her/his particular situation to the processing of data related to her/him, save where otherwise provided by national legislation; on occasion of a justified objection, these data shall be removed from the processing procedure that has been initiated by the pilot controller. To object, on demand without having to bear cost, to the procedure of processing personal information concerning her/him especially when the pilot controller foresees a procedure for commercial aims as well as to be given the right to object costless to such disclosures or uses.

6.5. Data Confidentiality and Security

- Confidential information must not be processed by any individual, working under the terms of command of the pilot controller or of the information data processor, with the processor inclusive, unless they are following orders of the controller, and only in situations where they are legally allowed to do so.
- The controller is expected to put in place the proper organizational and technical measures (e.g. PET technologies) to safeguard confidential information from accidental loss, alteration, unapproved leak or access, notably if the procedure entails the transfer of information data across a network, and from all other unlawful forms of processing.
- Acknowledging the level of sophistication and the implementation expenditure, such a situation requires a significant level of safeguarding procedures to balance with the level of threat confronted by such procedures as well as the type of the information to be safeguarded. Therefore, the implementation of processes by the processor must be bounded by a lawfully obligated act or contract that would tie the processor to the controller and specify exclusively that:
- The processor shall operate on the basis of nothing but the instructions of the controller
- The commitments, as described by the authorities charter for which the processor if established, shall also be binding on the processor

6.6. Installing of sensors – Notification

Before carrying out any information gathering procedure, the controller of the research and experimentation or his or her official delegate or associate, when available, must inform the supervisory authority (RAMCIP Ethic Advisory Board). The information to be given while informing them shall at least include the following:

- The name and address of the controller and her/his official delegate or representative, if available
- The aim of the data collection and processing procedure
- A description of the category or categories of data subjects and of the information or groups of information relating to them that shall be collected
- The receiver or groups of receivers to whom the information could be provided to
- A general overview enabling a preliminary evaluation to be made on the appropriateness of the measures taken to ensure the safeguarding and protection of the data processing procedure

The pilot trial areas (both: simulated environment in the room of Neurology Department -LUM and real houses of end-users in Spain-ACE) that will be observed with different kinds of sensors should be appropriately marked with Notification Posters, describing in detail the equipment used and monitoring procedures taking place towards the aims of the RAMCIP project.

All the participants of both pilot trials: in simulated and real home environments, and any person that may enter the monitored areas (families of end-users, social workers, medical personnel etc.) shall be well informed and their verbal approval should be requested. Before the pilot phase begins, participants taking part in the pilot trials will be required to sign an informed consent form.
Annex II: Provisional Ethics Approvals

Approval of the Ethics Committee at LUM - Original

W dniu 29 stycznia 2015 r. Komisia Bioetyczna przy Uniwersytecie Medycznym w Lublinie, Al. Racławickie 1 zapoznała się z projektem eksperymentu medycznego:
„Domowy robot asystent dla pacjentów z łagodnymi zaburzeniami poznawczymi” (akronim RAMCIP – Robotic assistance for MCI patients in home)

Projekt przedstawia:
Prof. dr hab. Konrad Rejdak
Katedra i Klinika Neurologii
Uniwersytetu Medycznego w Lublinie

Do Komisji wpłynęły następujące dokumenty:

Opis zadań
Protokół badania
Informacja dla Ochotnika/ Pacjenta
Formularz Świadomej Zgody Ochotnika/ Pacjenta na udział w badaniu
Umowa konsorcjum

Po zapoznaniu się z całością dokumentacji, zgodnie z zasadami GCP (Guidelines for Good Clinical Practice), Komisja Bioetyczna:
wyraziła pozytywną opinię o przedstawionym projekcie eksperymentu medycznego.

Niniejsza opinia traci moc z chwilą ukończenia badania.

PRzewodniczący

[Signature]

[Date]
Translation of the Approval of the Ethics Committees at LUM

RESOLUTION OF THE ETHICS COMMITTEE
Number KE-0254/8/2015

On the 29th of January 2015, the Ethics Committee at the Medical University of Lublin was introduced to a medical experimentation project:

“Robotic Assistant for MCI patients at home” (acronym RAMCIP)

The project was presented by:

Prof. Dr hab. Konrad Rajdak
Chair and Department of Neurology
Medical University of Lublin

The Committee received the following documents:
Tasks Description
Protocol
Patient/Volunteer Information
The form of Informed Consent for volunteer/patient to participate in the study
Consortium agreement

After being familiarized with all the documentation, in accordance with the principles of GCP (Guidelines for Good Clinical Practice), the Ethics Committee:
expressed positive opinion about the presented project of medical experimentation.
This opinion will be repealed upon the completion of the study.

Chairman of the Committee

Date
DICTAMEN DEL COMITÉ ÉTICO DE INVESTIGACIÓN CLÍNICA

NEUS RIBA GARCÍA, Secretaria del Comité Ético de Investigación Clínica del Hospital Clínic de Barcelona

Certifica:

Que este Comité ha evaluado la propuesta de la Fundació ACE, Institució Catalá de Neurociències Aplicades, para realizar la evaluación ética y metodológica del proyecto:

CÓDIGO: RAMCIP
VERSIÓN: 1.03 20140410

TÍTULO: Robotic Assistant for MCI patients at home.
INVESTIGADOR PRINCIPAL: AGUSTÍN RUÍZ LAZA

Y se compromete, una vez disponga del proyecto, a revisar los aspectos clínicos tanto éticos como metodológicos y a hacer el seguimiento del mismo.

y hace constar que:

1º En la reunión celebrada el día 12/02/2015, acta 3/2015 se decidió emitir el informe correspondiente al estudio de referencia.

2º El CEIC del Hospital Clínic i Provincial, tanto en su composición como en sus PNTs, cumple con las normas de BPC (CPNP/CH/135/95).

3º Listado de miembros:

Presidente:
- FRANCISCO JAVIER CARNE CLADELLAS (Médico Farmacólogo Clínico, HCB)

Vicepresidente:
- BEGOÑA GÓMEZ PEREZ (Farmacéutica Hospitalaria, HCB)

Secretario:
- NEUS RIBA GARCÍA (Médico Farmacólogo Clínico, HCB)

Vocales:
- IZQUIERDA DE LEUCONA (Jurista, Observatorio de Bioética y Derecho, UB)
- MONTserrat GONZÁLEZ CREUS (Trabajadora Social, Servicio de Atención al Usuario, HCB)
- MIKIMI MENDEZ GARCÍA (Abogada, HCB)
- MONTserrat NUÑEZ JUAREZ (Enfermera, HCB)
- JOSÉ RÍOS GUILERMO (Estadístico, Farmacología Clínica, USEM, UASP, HCB)

HOSPITAL CLÍNIC DE BARCELONA
Vallarcas, 120 - 08036 Barcelona (España)
Tel. 93 227 54 00 Fax 93 227 54 54
www.hospitalclinic.org

Comité de Ética de la Institución de la pomiędzy de playa
DICTAMEN DEL COMITÉ ÉTICO DE INVESTIGACIÓN CLÍNICA

NEUS RIBA GARCIA, Secretaria del Comité Ético de Investigación Clínica del Hospital Clínic de Barcelona

Certifica:

Que este Comité ha evaluado la propuesta de la Fundació ACE. Institut Català de Neurociències Aplicades, para realizar la evaluación ética y metodológica del proyecto:

CÓDIGO: RAMCIP  
VERSIÓN: 1.83 2014-04-10

TÍTULO: Robotic Assistant for MCI patients at home.  
INVESTIGADOR PRINCIPAL: AGUSTÍN RUIZ LAZA

Y se compromete, una vez disponga del proyecto, a revisar los aspectos clínicos tanto éticos como metodológicos y a hacer el seguimiento del mismo.

y hace constar que:

1º En la reunión celebrada el día 12/02/2015, acta 3/2015 se decidió emitir el informe correspondiente al estudio de referencia.
2º El CEIC del Hospital Clínic i Provincial, tanto en su composición como en sus PNTs, cumple con las normas de BCP (CPMP/ICH/135/95)
3º Listado de miembros:

Presidente:
- FRANCISCO JAVIER CARNE CLADELLAS (Médico Farmacéutico Clínico, HCB)

Vicepresidente:
- BEGOÑA GÓMEZ PEREZ (Farmacéutico Hospitalaria, HCB)

Secretario:
- NEUS RIBA GARCIA (Médico Farmacéutico Clínico, HCB)

Vocales:
- ITZAR DE LEIZUNA (Jurista, Observatorio de Bioética y Derecho, UB)
- MONTSERRAT GONZALEZ CREUS (Trabajadora Social, Servicio de Atención al Usuario, HCB)
- MIRIAM MENDEZ GARCÍA (Abogada, HCB)
- MONTSERRAT NUÑEZ JUAREZ (Enfermera, HCB)
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Month-M05 59  Lead Partner- LUM
ANEX III: Sample of the standard informed consent at LUM

Note: the original was prepared in Polish

INFORMED CONSENT FORM VOLUNTEER
PARTICIPATION IN WORKSHOPS

Title of study:
"Domestic robot assistant for patients with mild cognitive impairment"

Name: ____________________________
Date of birth: ______________________
Occupation: ________________________

I, the undersigned, certify that I have read and understood the information for Volunteer and received satisfactory answers to my questions. I voluntarily agree to participate in the workshops and I am aware of, that at any time I can stop participating in them for any reason.

Pursuant to Art. 23, Paragraph. 1 point 1 of the Act of 29 August 1997 on the protection of personal data (Dz. U. 2002. No. 101, item 926, as amended. D.) I agree to the processing by the Medical University of Lublin, located at Al. Bocławicka 1, 20-059 Lublin my personal data within the scope and purpose necessary to carry out workshops, as well as archival and statistical purposes.

I have knowledge of the voluntary application data. I was also informed that I have the right to access data concerning me, to correct, modify, and use other rights resulting from the above Act.

Attachment:
1) Information about the workshops
## Annex IV: Potential Ethical Hazardous Events

<table>
<thead>
<tr>
<th>Hazardous event</th>
<th>Detailed description</th>
<th>Mean of identification</th>
<th>Level of controllability</th>
<th>Mitigation strategy</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reduction of the human contact</td>
<td>Potential threat of restricting the gained help exclusively to the robotic assistant</td>
<td>Decreasing of the interest from the human caregiver</td>
<td>HIGH</td>
<td>Social contact supported by implementing UC8- “Support in socialization, positive affect and mental stimulation” Control of HRI provided by professionals of Trial sites.</td>
</tr>
<tr>
<td></td>
<td>Possible reduced social contact</td>
<td>Reduced interest in social activities and social withdrawal</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Increased feeling of objectification</td>
<td>By providing help without proper recognition of the human needs</td>
<td>Increased level of stress and withdrawal</td>
<td>HIGH</td>
<td>Psychological interview, tests provided by psychologists and close cooperation with patient’s relatives and caregivers required. Continuous observation and control of HRI provided by professionals of Trial sites.</td>
</tr>
<tr>
<td></td>
<td>Performing activities against the human will</td>
<td>Decreased motivation to cooperation with the robot and the researcher</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Reduced possibility to performed activities according to the human preferences</td>
<td>Refusing giving feedback information</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Restraining oneself from performing actions of interest</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Loss of control</td>
<td>Reduced possibility to influence the outcome and performance of an activity</td>
<td>Decreased motivation to cooperation with the robot and the researcher</td>
<td></td>
<td>Monitoring of patient’s behaviour provided by psychologists and physicians. Cooperation with family</td>
</tr>
<tr>
<td></td>
<td>Disability to stop</td>
<td>Refusing giving</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
| Loss of Privacy | Decreased motivation to cooperation with the robot and the researcher | HIGH | Data security control rules:  
- processing of visual data  
- immediate erasing of all data  
- secured computers at trial partners  
- continual monitoring of EAB  
- periodic reports to Local Ethical Committee |
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Loss of Liberty</td>
<td>Declining the human from possibility of choosing the preferred way of performing the activity</td>
<td>HIGH</td>
<td>Detection and evaluation of actions taken against the patient’s will. Continuous professional monitoring required.</td>
</tr>
<tr>
<td>Loss of Autonomy</td>
<td>Declining the human from taking autonomous decisions</td>
<td>HIGH</td>
<td>Detection and evaluation of actions taken against the patient’s will. Continuous professional monitoring required.</td>
</tr>
</tbody>
</table>
Deception and infantilisation

<table>
<thead>
<tr>
<th>Condition</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Refusing giving feedback information</td>
<td>Monitoring required.</td>
</tr>
<tr>
<td>Restraining oneself from performing actions of interest</td>
<td></td>
</tr>
<tr>
<td>Deception and infantilisation</td>
<td>By partial information or the style of communication (vocabulary used)</td>
</tr>
<tr>
<td>Confusion declared by the patient</td>
<td>HIGH</td>
</tr>
<tr>
<td>Visible disorientation of the human</td>
<td>Detection of improper vocabulary usage.</td>
</tr>
<tr>
<td>Prolonged hesitation of the human</td>
<td>Comparison of the current state to Robotic Assistant behaviour.</td>
</tr>
</tbody>
</table>

References: