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CERTH	Centre for Research and Technology Hellas	Greece
INRIA	Institut National de Recherche en Informatique et en Automatique	France
WUT	Politechnika Warszawska	Poland
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Project Abstract

The RAPP project will provide an open-source software platform to support the creation and delivery of Robotic Applications (RApps), which, in turn, are expected to increase the versatility and utility of robots. These applications will enable robots to provide physical assistance to people at risk of exclusion, especially the elderly, to function as a companion or to adopt the role of a friendly tutor for people who want to partake in the electronic feast but don't know where to start.

The RAPP partnership counts on seven partners in five European countries (Greece, France, United Kingdom, Spain and Poland), including research institutes, universities, industries and SMEs, all pioneers in the fields of Assistive Robotics, Machine Learning and Data Analysis, Motion Planning and Image Recognition, Software Development and Integration, and Excluded People. RAPP partners are committed to identify the best ways to train and adapt robots to serve and assist people with special needs.

To achieve these goals, over three years, the RAPP project will implement the following actions:

- Provide an infrastructure for developers of robotic applications, so they can easily build and include machine learning and personalization techniques to their applications.
- Create a repository, from which robots can download Robotic Applications (RApps) and upload useful monitoring information.
- Develop a methodology for knowledge representation and reasoning in robotics and automation, which will allow unambiguous knowledge transfer and reuse among groups of humans, robots, and other artificial systems.

- Create RApps based on adaptation to individuals and taking into account the special needs of elderly people, while respecting their autonomy and privacy.
- Validate this approach by deploying appropriate pilot cases to demonstrate the use of robots for health and motion monitoring, and for assisting technologically illiterate people or people with mild memory loss.

The RAPP project will help to enable and promote the adoption of small home robots and service robots as companions to our lives. RAPP partners are committed to identify the best ways to train and adapt robots to serve and assist people with special needs. Eventually, our aspired success will be to open and widen a new 'inclusion market' segment in Europe.

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List of Abbreviations

ABBREVIATION	DEFINITION
RAPP	A Sofware Platform to deliver smart, user empowering Robotic Applications
FRE	Framework for Research Ethics
IMIA	International Medical Informatics Association
HIPs	Health Informatics Professionals
EAT	Electronic Assistive Technology
WMA	World Medical Association
CCTV	Closed Television Circuits
LOPD	Spanish Organic Law for the Protection of Personal Data

Executive summary

The present document is a deliverable of the RAPP project, funded by the European Commission's Directorate-General for Communications Networks, Content & Technology (DG CONNECT), under its 7th EU Framework Programme for Research and Technological Development (FP7).

Humans will be involved throughout the RAPP project and to be more precise older people at risk of exclusion such as technology illiterates, older people diagnosed with Mild Cognitive Impairment (MCI) and elderly people with mobility impairment, along with caregivers and health professionals. Personal data acquisition, storage and process will take place which requires the accomplishment of the European as well as the national regulatory legislation.
Therefore, ethical considerations play an important role within the RAPP project. This deliverable D1.5 of WP1 addresses the way in which ethical issues are going to be considered in RAPP in order to ensure that users' rights are fully guaranteed at the different stages of the project.
The deliverable includes ethical and regulatory concerns regarding research at European level while it also identifies important national Greek and Spanish legislation related to processing of personal data and Ethics Committee. Moreover, it describes the ethical issues involved in RAPP, the possible risks and the ethical documents taken into account. Finally a Data Protection Plan is defined.

Introduction

Ethical considerations play an important role when humans are involved as data subjects in research. Although RAPP project is not an e-health but rather an e-inclusion project, it aims at supporting autonomy, social inclusion and quality of life of the end user. Therefore it involves the assessment of the feasibility, acceptability, security, robustness, reliability, privacy and accessibility of systems and services given through genuine innovative robotic devices. The project includes the capacity of the system to be used for cognitive training monitored by specialized caregivers, mobility rehabilitation, detection of critical situations that may need connection with medical services and medicine reminders in the daily agenda. To this end, personal data concerning patients and caregivers involved in the research will be collected and stored in a project database. Therefore, ethic rules concerning personal data such as medical and health data have to be considered.

1. Ethical and regulatory concerns regarding research

Research activities related to humans raise important ethical questions and need thorough deliberation before and during the planning and implementation of research activities.
Within this section, recommendations of several Groups of Experts and Associations on Ethics at European level, as well as the Helsinki Declaration will seriously be taken into account.

1.1 The Research Ethics Framework

According to the Framework for Research Ethics FRE[1], the principal aim of the ethics review is, as far as possible, to protect all groups involved in research: participants, institutions, funders and researchers throughout the lifetime of the research and into the dissemination process. Research organisations should have clear, transparent, appropriate and effective procedures in place for ethics review, approval and governance whenever it is necessary. Hence, research should be designed in a way that the dignity and autonomy of research participants are protected and respected at all times.

Like the aforementioned, the updated in September 2012 version of the Framework[2] maintains that, social research should comply with the following demand:

> *"Social scientists should ensure that research participants are aware of and consent to arrangements made with regard to the management and security of data, the preservation of anonymity, and any risk that might arise during or beyond the project itself, and how these might be minimised or avoided."*

This, however, imposes certain limitations upon the very design of the research process and conduct, which should be under scrutiny of an autonomous body[1]:

> *"While ethical principles and review concern the rights, dignity and safety of standards and mechanisms that permit the proper management and monitoring of research and, if necessary, allow sanctions to be brought in cases of research misconduct. These two dimensions are linked. It is clear that a strong ethical culture and literacy are dependent not only on professional self-regulation but also on sound structures of formal governance within research organisations."*

[1] ESRC Framework for Research Ethics (FRE) 2010 Updated September 2012
http://www.esrc.ac.uk/_images/framework-for-research-ethics-09-12_tcm8-4586.pdf

[2] Research Ethics Framework.
http://www.esrc.ac.uk/esrcinfocentre/images/esrc_re_ethics_frame_tcm6-11291.pd

According to this organization the following six listed principles are the key ones concerning ethical research:

1. Research should be designed, reviewed and undertaken to ensure integrity, quality and transparency.

2. Research staff and subjects must be fully informed about the purpose, methods and possible intended use of the research, what their participation in the research entails and what risks, if any, are involved.

3. The confidentiality of information supplied by research subjects and the anonymity of respondents must be respected.

4. Research participants must take part voluntarily, free from any coercion.

5. Harm to research participants and researchers must be avoided.

6. The independence of research must be clear, and any conflicts of interest or partiality must be explicit.

To implement these principles:

- The responsibility for conducting the research in line with relevant principles rests with the principal investigator and the research / employing organization.
- The responsibility for ensuring that research is subject to appropriate ethics review, approval and monitoring lies with the research organization seeking or holding an award with the ESRC, which employs the involved researchers or some of the researchers when the Research Organization is acting as the coordinator for collaborative research involving more than one organization. This responsibility also applies to research organizations hosting ESRC students and visiting researchers.
- Research organizations should have clear, transparent, appropriate and effective procedures in place for ethics review, approval and governance whenever it is necessary.
- Risks should be minimized.
- Research should be designed in a way that the dignity and autonomy of research participants is protected and respected at all times.
- Ethics review should always be proportionate to the potential risk, whether this involves primary or secondary data.

Following these ethical principles the researchers ensure that their investigation will take place with high ethical standards.

1.2 IMIA Code of Ethics for Health Information Professionals (HIPs)

The International Medical Informatics Association (IMIA) is an independent organization established under Swiss law in 1989[3].

IMIA plays a major global role in the application of information science and technology in the fields of healthcare and research in medical, health and bioinformatics. The basic goals and objectives of the association are to:

- promote informatics in health care and research in health, bio and medical informatics.
- advance and nurture international cooperation.

[3] About International Medical Informatics Association
http://www.imia-medinfo.org/new2/node/1

- stimulate research, development and routine application.
- move informatics from theory into practice in a full range of health delivery settings, from physician's office to acute and long term care.
- promote the dissemination and exchange of knowledge, information and technology.
- promote education and responsible behaviour.
- represent the medical and health informatics field within the World Health Organization and other international professional and governmental organizations.

In its function as a bridge organization, IMIA's goals are:

- moving from theory into practice by linking academic and research informatics with care givers, consultants, vendors and vendor-based researchers.
- leading the international medical and health informatics communities throughout the 21st century.
- promoting the cross-fertilization of health informatics information and knowledge across professional and geographical boundaries.
- serving as the catalyst for ubiquitous worldwide health information infrastructures for patient care and health research.

The IMIA Code presents a list of fundamental ethical principles[4]:

- **Principle of Autonomy**: All persons have a fundamental right to self-determination.
- **Principle of Equality and Justice**: All persons are equal and have the right to be treated accordingly.
- **Principle of Beneficence**: All persons have a duty to advance the good of others, where the nature of this good is in keeping with the fundamental and ethically defensible values of the affected party.
- **Principle of Non-Malfeasance**: All persons have a duty to prevent harm to other persons insofar as it lies within their power to do so without unnecessary harm to them.
- **Principle of Impossibility**: All rights and duties hold subject to the condition that is possible to meet them under the circumstances that obtain.
- **Principle of Integrity**: Whoever has an obligation has a duty to fulfil that obligation to the best of her or his ability.

These fundamental ethical principles, when applied to the types of situations that characterize the informatics setting, give rise to general ethical principles of informatics:

- **Principle of Information-Privacy and Disposition**: All persons have a fundamental right to privacy, and hence to control over the collection, storage, access, use, communication, manipulation and disposition of data about themselves.
- **Principle of Openness**: The collection, storage, access, use, communication, manipulation and disposition of personal data must be disclosed in an appropriate and timely fashion to the subject of those data.

[4] The IMIA Code of Ethics for Health Information Professionals
http://www.imia-medinfo.org/new2/pubdocs/Ethics_Eng.pdf

- **Principle of Security**: Data that have been legitimately collected about a person should be protected by all reasonable and appropriate measures against loss, degradation, unauthorized destruction, access, use, manipulation, modification or communication.

- **Principle of Access**: The subject of an electronic record has the right of access to that record and the right to correct the record with respect to its accurateness, completeness and relevance.

- **Principle of Legitimate Infringement**: The fundamental right of control over the collection, storage, access, use, manipulation, communication and disposition of personal data is conditioned only by the legitimate, appropriate and relevant data-needs of a free, responsible and democratic society, and by the equal and competing rights of other persons.

- **Principle of the Least Intrusive Alternative**: Any infringement of the privacy rights of the individual person, and of the individual's right to control over person-relative data as mandated under Principle of Information-Privacy and Disposition, may only occur in the least intrusive fashion and with a minimum of interference with the rights of the affected person.

- **Principle of Accountability**: Any infringement of the privacy rights of the individual person and of the right to control over person-relative data must be justified to the affected person in good time and in an appropriate fashion.

In the rest of the IMIA's document, a list of Rules of Ethical Conduct is presented revolving around the following topics: Subject centred duties; duties towards institutions/employers; duties toward society; self-regarding duties; and duties towards the profession (IMIA). See also European Federation for Medical Informatics[5] .

1.3 Electronic Assistive Technology (EAT)

The increasing availability of electronic technology at home, school and workplace has enhanced popular awareness of its potential for countering impairment, either congenital or resulting from illness or injury. People with disabilities are able to realize a great potential, to develop independence and become less dependent on others.
The rapidity of technological progress has outpaced the ability of the National Health Service to safely deliver an effective, integrated provision. This Report highlights current difficulties and makes recommendations to healthcare commissioners which offer real opportunity to promote and develop efficient, cost effective and equitable services nationwide. It builds upon and complements the Audit Commission's Report on the Provision of Equipment to Older or Disabled People by the NHS and Social Services in England and Wales.

Key recommendations arising from this report are[6]:

1. Electronic Assistive Technology (EAT) should be available equitably, appropriately and in a manner which is both efficient and cost-effective. Its provision should follow on from total disability assessment and should be considered a specialist component of Rehabilitation Medicine.
2. Comprehensive holistic assessment necessitates that a potential user's problems are properly identified and delineated. Whilst this may often be possible at a local level, complex problems demand that dedicated medical,

[5] European Federation for Medical Informatics
http://www.gsf.de/imei/efmi/

[6] Electronic Assistive Technology
http://www.bsrm.co.uk/Publications/EATabstract.pdf

scientific , technological, and therapy expertise should be available at a network of specialist centres. These centres should relate to local services on a "hub and spoke" basis.

3. Service delivery should be timely and appropriate. It should be overseen from each hub by specialist personnel who should adopt responsibility for equipment procurement, provision and maintenance. Working closely with locally based professional colleagues they should promote the effective, efficient and safe usage of EAT.
4. Technological advances necessitate that professional organisations such as the British Society of Rehabilitation Medicine, the Institute of Physics & Engineering in Medicine, the College of Occupational Therapists and the Royal College of Speech & Language Therapists work together and with healthcare commissioners to refine strategic objectives, to develop common integrated patterns of service delivery and to actively promote research and professional training.
5. There is need to define and establish national standards for the provision of EAT with accredited regional centres collaborating one with another to develop evidence based practice and oversee service delivery.

1.4 Assistive technology for people with dementia

Like any new idea or invention, assistive technology and telecare has the potential to be of benefit but it also has the potential to be misused. It is important to understand that it can be both things at once; that is any device may be beneficial in some respects but may also have costs to the person with dementia or their caregivers. Some of those costs may be hidden or not apparent until later. For example there may be concerns:

- about particular types of device, such as those used more for monitoring safety, and how they may affect the privacy or freedom of a person with dementia.
- about the impact of assistive technology and telecare on society. For example, the fear that it may be used to cut back services and reduce human contact.
- some devices may be used to do things that a person is still able to do for themselves which may make their problems worse.
- that they may make things more complicated or beyond the abilities of the person.
- that they may help foster a one-sided focus on a person's problems and not on their existing strengths.
- about the use of technological solutions, especially those that may restrict freedom or privacy, without fully involving or obtaining the consent of the person with dementia.
- about the use of computer technologies that rely on sharing information and ensuring such information is not misused or allowed to fall into the wrong hands.

To ensure these points are being accomplished, the 4 principles of modern medicine can be adapted[7]. These are the principles of Non-maleficence, Beneficence, Autonomy and Justice.

- **Non-maleficence** simply means “do no harm”. In other words we need to ask ourselves “are we in danger of doing more harm than good?”. For example, considering whether there is a risk that a piece of equipment may lead to more confusion or distress.
- **Beneficence** means striving consciously to be “of benefit” to the person. In other words the intention should be to benefit the person with dementia as for example by enabling access to support or help if they fall or helping them to take their medication.
- **Autonomy** refers to respecting the person’s rights to things like self-determination, privacy, freedom, and choice. So for example, if a device such as a sensor mat is used to help monitor falls risk, would it be used just to tell the person not to walk or get up or would the person be offered a companion to walk with safely?
- **Justice** means treating everyone fairly. For example providing equal access to technology, or taking into account diversity and individual differences.

[7] Information on Assistive technology for people with dementia
http://www.atdementia.org.uk/content_files/files/The_ethical_use_of_assistive_technology.pdf

Assistive technology is any technology that helps people to do things that are beyond their reach. This can also include being able to maintain relationships or keep in contact with loved ones, being able to remember events, or being able to carry out a task. So researchers should think about how technology could be used to help persons achieve things they are finding harder to do, and how it can raise the quality of their life and their relationships.
How technology is used depends on us and that is where ethics come in. It's about making sure that the person with dementia is kept at centre of any decisions. We must avoid seeing them just as people at risk and in need of help. They are also people who will still have many abilities, needs and wishes of their own. We need to consider ways to involve the person with dementia and to gain their informed consent instead of making assumptions that the person with dementia cannot give consent Capacity to give consent is not something a person either has or does not have. It often depends on the situation and how the issue is presented. So this may require finding the best approach to consult with them about the devices or services being considered. This may include using verbal and nonverbal approaches such as pictures, videos or real examples of the technology involved.
Regarding RAPP, the people involved do not suffer from dementia, but mild cognitive impairment which means that gaining their informed consent shouldn't require any special approach, only a clear explanation. In any case, the procedure to obtain the consent should be adapted to the capacities of the people involved.

1.5 Helsinki declaration

The World Medical Association (WMA) has developed the Declaration of Helsinki as a statement of ethical principles to provide guidance to physicians and other participants in medical research involving human subjects. Medical research involving human subjects includes research on identifiable human material or identifiable data. Although the RAPP project is not a medical research project, health data such as morbidity or medication will be collected, and health professionals will be involved in the project too, therefore ethical issues concerning medical and health data have to be considered.

These are the general principles of the Helsinki declaration, seventh revision of 2013[8].

1. The Declaration of Geneva of the WMA binds the physician with the words, "The health of my patient will be my first consideration," and the International Code of Medical Ethics declares that, "A physician shall act in the patient's best interest when providing medical care."

2. It is the duty of the physician to promote and safeguard the health, well-being and rights of patients, including those who are involved in medical research. The physician's knowledge and conscience are dedicated to the fulfilment of this duty.

3. Medical progress is based on research that ultimately must include studies involving human subjects.

4. The primary purpose of medical research involving human subjects is to understand the causes, development and effects of diseases and improve preventive, diagnostic and therapeutic interventions (methods, procedures and treatments). Even the best proven interventions must be evaluated continually through research for their safety, effectiveness, efficiency, accessibility and quality.

5. Medical research is subject to ethical standards that promote and ensure respect for all human subjects and protect their health and rights.

[8] WorldMedical Association Declaration of Helsinki Ethical Principles for Medical Research Involving Human Subjects http://jama.jamanetwork.com/ on 04/15/2014

6. While the primary purpose of medical research is to generate new knowledge, this goal can never take precedence over the rights and interests of individual research subjects.

7. It is the duty of physicians who are involved in medical research to protect the life, health, dignity, integrity, right to self-determination, privacy, and confidentiality of personal information of research subjects. The responsibility for the protection of research subjects must always rest with the physician or other health care professionals and never with the research subjects, even though they have given consent.

8. Physicians must consider the ethical, legal and regulatory norms and standards for research involving human subjects in their own countries as well as applicable international norms and standards. No national or international ethical, legal or regulatory requirement should reduce or eliminate any of the protections for research subjects set forth in this Declaration.

9. Medical research should be conducted in a manner that minimises possible harm to the environment.

10. Medical research involving human subjects must be conducted only by individuals with the appropriate ethics and scientific education, training and qualifications. Research on patients or healthy volunteers requires the supervision of a competent and appropriately qualified physician or other health care professional.

11. Groups that are underrepresented in medical research should be provided appropriate access to participation in research.

12. Physicians who combine medical research with medical care should involve their patients in research only to the extent that this is justified by its potential preventive, diagnostic or therapeutic value and if the physician has good reason to believe that participation in the research study will not adversely affect the health of the patients who serve as research subjects.

13. Appropriate compensation and treatment for subjects who are harmed as a result of participating in research must be ensured.

2. Identification of any important national regulations

2.1 Spain-Ethics committee and laws

2.1.1 The Ethics Committee of the Matia Foundation

Matia Foundation is a non-profit organization with private management founded in 1888 for social care and health assistance of elderly and disabled people. Matia Institute is the health and social research centre of Matia Foundation set up to develop interdisciplinary research on aging and disability. Spanish legislation requires (although there is no legal obligation) that all experimental investigation protocols with human beings have been favourably evaluated by an Ethics Committee at the beginning of the study. Matia Foundation has its own Ethics Committee since 2001 which was accredited by Resolution of the Basque Country Government in 2007.

Matia Institute as part of Matia Foundation has the obligation to regulate all of its research according to Matia Foundation's Ethics Committee regulations. This Ethics Committee is a consultative organ that analyses and advises in those situations and cases that can be problematic from the ethical perspective, as well as legal standpoint. The aim of this Ethics Committee is to guarantee the best quality of the social, psycho-social and public health attention that Matia Foundation and Matia Institute provides to elderly people and persons with disabilities and their relatives. Its objectives focus on ensuring the fundamental ethical principles such as integration in society, leading a normal life, confidentiality

and others. The Ethics Committee also establishes the criteria that should be followed to guarantee the rights of its users. All the research conducted by Matia Foundation and Matia Institute must be evaluated by this committee.

2.1.2 The Research Committee of the Matia Foundation

We have set out above the Ethics Committee of the Matia Foundation's ethical guidelines on Clinical Research on human beings. However, ethical issues should be taken into account not only before the research on human beings is performed. Research Committees are also necessary to monitor the correct progression of the research. The Matia Foundation has its own Research Committee which offers the overview and the approval of all the investigation carried out in the Matia Foundation and Matia Institute.

This Research Committee is made up of professionals from the Matia Foundation, Matia Institute and other public entities. The most important objective of this committee is the promotion and development of research projects associated with the elderly and people with physical and/or cognitive disabilities. Another objective is to collaborate with institutions related to research and medical assistance, and particularly those which are related to elderly. The third aim is related to the development of rigorous research as well as to the ethical quality of the investigations in general and the results in particular. The last purpose is to spread the knowledge linked to publications, reports or any other method of scientific or academic dissemination.

The research committee promotes advises and supports all research projects, carried out by the Matia Foundation, Matia Institute or other entities, in their process of development, finishing and publication. Another function of this committee is to advise and to control the methodology, scientific and ethical issues of the ongoing projects. It will make at least two assessments, one at the beginning and another one when the project has finished. For this reason, the Committee is informed of all the research proposals in Matia Foundation or Matia Institute. Finally, another role of this committee is to promote training and methodological qualification of the researches.

The specific areas of work of this committee are those related to medicine, social science and behaviour, and especially bioethical issues. The Committee complies with the criteria of Good Clinical Practice in Investigation, according to the last proposal of the Agreement of Helsinki, directives of the Agreement of Oviedo and their applications in the Spain.

2.1.3 Personal Data Protection Act [15/1999]

The issue of personal data protection is well covered by national legislation dealing with handling of personal data (namely Organic Law 15/1999 for the Protection of Personal Data, LOPD)[9] which is harmonised with European Directive 95/46/EC[10]. This law corresponds with the requirements embedded in EU legislation, Directive 95/46/EC on the protection of individuals with regard to processing of personal data and on the free movement of such data.

2.1.4 Patient autonomy and rights on clinic documentation Act [41/2002]

Ethical issues of scientific work with patients are recognized in Law 41/2002. In Article 2 all the basic aspects about human dignity, appropriate information required and written informed consent are described. Consent is only valid if the subject of the research has previously been given information concerning the research. The consent is to be voluntary, explicit and specific to the particular research that has been carried out.

2.1.5 Public Health Act [14/1986]

Ethical issues about patient care and research are covered also by Law 14/1986, particularly in Title VI and chapter II about research with patients. Information about the research has to be provided on: the overall plan, research purpose, the methods that will be used, all the consequences and risks that this research might entail, the identity of the responsible research body, the fact that participation in the research is voluntary and the right of the subject to cease participating at any time.

[9] Spanish Law 15/1999 on Protection of Personal Data
http://www.agpd.es/portalwebAGPD/english_resources/regulations/common/pdfs/Ley_Orgaica_15-99_ingles.pdf

[10] European Directive 95/46/EC
http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31995L0046:en:HTML

2.1.6 Equal opportunity, no discrimination and universal accessibility of handicapped people: Independent living/accessibility Act [51/2003]

Ethical issues about persons with disabilities are covered by law 51/2003. This law recognises and respects the right of people with disabilities to benefit from measures designed to ensure their independence and accessibility.

2.2 Greek laws and Ethics Committee

2.2.1 The Ethics Committee of "ORMYLIA" Foundation

"ORMYLIA" Foundation is a non-profit, non-governmental institution supervised by the Ministries of Development, Culture, Education and Health. "ORMYLIA" Foundation, in its two divisions, the Diagnosis Centre and the Centre for Social Advancement, Medical Prevention and Research, "Panagia Philanthropini", has an average number of more than 1000 of individual external users per year (mainly minorities and impoverished). From its inception the Foundation has sought to collaborate with premier medical centers from around the world so as to insure that the standardized medical service be of the highest quality possible.

In the 1990s the European Union recognized "ORMYLIA" Foundation as a European Union Center of Excellence and included the Foundation in the networks for cervical and breast cancer. The Center continues to be a member of this European consortium and is a contributing author of the European Guidelines in both fields.
"ORMYLIA" Foundation is an active research institution supervised and supported by the institution's Ethical Committee. The aim of this committee is to assist the conduct of medical and social research within the rules of medical ethics and ethics that underpin social research. To achieve this, advice and guidance on research planning is provided to researchers.
The ethics of research conduct follow all relevant laws and are consistent with the instructions of the Medical Association and the institutions of the European Union as well as the content of the Declaration of Helsinki and the Instructions on the Practice of Ethics' Committees (3rd edition , Royal College of Physicians of London). Two fundamental rules of research conduct are followed: a) compliance with the accepted ethic rules of medical science, and b) precise information and consent of the patient.
The basic purpose of the Ethics Committee is to approve or reject proposals for research in various fields of medicine such as in the prevention and treatment of cancer or other research protocols to be carried out at the premises of the Foundation with the consent of the Committee. Not any research proposal will be approved if a member state of the Committee disagrees or is unable to support it.
The Foundation's Ethical Committee collaborates with other Research and Ethical Committees, in cases that this collaboration is needed, while preserving their independence and responsibilities regarding the specific areas of specialized research in which it operates.

2.2.2 Protection of Individuals with regard to the Processing of Personal Data Act [2472/1997]

Data protection in Greece is basically provided for by Law 2472/1997[11], which harmonized the Greek legislation with Directive 95/46/EC. This Law institutes a set of obligations for those ones who process personal data and respective rights of the people to whom the data processed relate. The same Law does also provide for the establishment of the Hellenic Data Protection Authority (HDPA).
The object of this law is to establish the terms and conditions under which the processing of personal data is to be carried out so as to protect the fundamental rights and freedoms of natural persons and in particular their right to privacy.

[11] Greek Law 2472/1997
http://www.dpa.gr/pls/portal/docs/PAGE/APDPX/ENGLISH_INDEX/LEGAL%20FRAMEWORK/LAW%202472-97-APRIL010-EN%20_2_.PDF

Additionally, when it comes to special cases of personal data processing, other laws may apply as well: e.g. Law 3471/2006 re personal data protection in the sector of electronic communications (vide Directive 2002/58/EC), Law 3917/2011 re the retention of data processed within the framework of public electronic communications (vide Directive 2006/24/EC), article 34 of Law 4002/2011 re the processing of personal data conducted by the Gaming Supervision & Control Commission within the framework of the Gaming Market regulations etc.

2.2.3 Directive of Closed Television Circuits (CCTV) 26/09/2000

Regarding the directive of Closed Television Circuits (CCTV)[12] held out by Hellenic Data Protection Authority:

1. According to article 2 part a) of Law 2472/1997 and EC Directive 94/46, audiovisual data, when relating to individuals, are considered to be personal data,
2. Storage and transmission of image of an individual, recorded by a fixed closed circuit television, operating on a regular, continuous or permanent basis, outdoors or indoors, such as on streets, squares, stations, ports, stadia, in banks, stores, theatres, cinemas, or public transportation means, constitute processing of personal data, in the terms of article 2 par. d of Law 2472/1997,
3. The mere recording of such an image by a closed circuit television, without it being stored or further processed, does not exempt the Controller from the obligation to notify to the Data Protection Authority said recording and inform the data subjects accordingly, in the terms of articles 6 and 11 of Law 2472/1997,
4. According to article 19 par. 1 section a of Law 2472/1997, the Data Protection Authority shall issue directives for the purpose of a uniform application of the rules pertaining to the protection of individuals with regard to the processing of personal data

3. Ethical Issues at RAPP

3.1 Identification of ethical issues involved in the project

1. Loss of autonomy: Considering that our subject groups are elderly with health issues, it is obvious that they represent a vulnerable group that can be easily manipulated. To avoid that, their participation in the program must be voluntary and autonomous and they should be provided with full information about the project. This information will be detailed and adapted to their understanding level ensuring that in the moment of taking the decision they are fully capable of making that choice consciously.

   On the other hand, they will be free to retire from the project whenever they want.

2. Loss of confidential information: As in any project based primarily in information compilation, there is a risk of losing data that is personal or confidential. The NAO robot is equipped with cameras which record activities or take pictures of the assisting elders therefore they must be protected against any third party viewer trying to reach this sensitive data. Same goes for the data recorded by the rollator. Once digitalized, the data should be encrypted to ensure there is no data loss.

3. Security: It must be taken into consideration, that when testing the ANG rollator there is some risk of falling. The design of the apparatus must be as safe as possible to avoid any unnecessary risk. In any case, should an accident happen during the pilot testing, the user will be covered by Matia's insurance.

4. Dependency: When using assistive technology, there is a risk that this technology does more than the user actually needs. In these cases, technology might contribute to a deterioration of some faculties that the user

[12] Directive of Close Television Circuits (CCTV) 26/09/2000
http://ec.europa.eu/justice/policies/privacy/policy_papers/docs/greece/directive_1122_26.09.2000_cctv.pdf

maintain in healthy and normal conditions. This creates an over dependency of the user toward the assistive technology.

5. Surveillance: NAO robot is equipped with cameras and microphones which can follow user's daily activities, take pictures and videos of specific activities or record audio files and send them to the cloud. This camera can take photos on a regular basis when activated, to upload to the RAPP Platform in order to perform object identification or fall detection algorithms. On the other hand the rollator monitors users' walking pattern and activity. Although surveillance data is very interesting for the sake of the users, it must be limited, with pre-established boundaries so to avoid any unnecessary personal data to be recorded. The interest of the user must be of top priority and the recorded data should be limited to those necessary to assist the user.

6. Malicious attacks: Every new technology is plagued by known and/or unknown weaknesses, which threaten to serve as the backdoor for malicious attackers.

3.2 Possible risks

In the following lines we will describe some risks identified within the RAPP project. The ethical issues before, during and after the evaluations are explained:

- Representativeness of the sample: The sample used in the project may not be representative of the target population. The same goes for the information collected in the different tasks, which can be non-adequate or insufficient for the goals of the RAPP project. In order to avoid these risks, the selection criteria and the assessment protocol will be properly defined before evaluations start.

- Voluntary participation: The participation of the subjects has to be strictly voluntary. Therefore, each time the participants carry out a test, evaluation or another kind of participation, they must give their informed consent, which means that the proposed procedure and its implications will be discussed, and only afterwards will the participant sign the relevant formulary. In the informed consent process the following parts are to be discussed:

    - Aim of the study
    - Voluntary nature
    - Risks/ Benefits
    - How the information is stored?
    - How the information is encoded?

- Data management: During the trials, the partners of the project have to share participants' personal and private information. One of the most important risks is related to the privacy and data handling. For this reason, it is important that the data will be encrypted or protected with a code during the storage and process. Likewise, the information saved into an interactive cloud will be strictly anonymous and it only can be used for other projects or robots for research purposes.
  Each partner should store the information in a secure way and the database must be sealed from people not involved in the project but working in the organization. The data will be saved for five years after the end of the project. After this time, each partner will be responsible for destroying the personal data in his organization.

- Security of the devices: There is a possibility that the robots used within the RAPP project could not be adapted to the needs and requirements of the users. The failure of some devices' characteristics and functionalities could produce (direct or indirectly) damage to the participant. For instance, the size of the NAO robot could trigger the participant's stumble and fall.

3.3 Ethical documents

3.3.1 Informed consent

Informed consent is the process by which a participant will be fully informed about the research in which he/she is going to participate. It originates from the legal and ethical right of the participant to direct what happens to his / her personal data and from the ethical duty of the investigator to involve the participant in research.
Respect for persons requires that participants, to the degree they are capable of, will be given the opportunity to choose what shall or shall not happen to them. This opportunity is provided, when adequate standards for informed consent are satisfied.
In order to involve a human being as a participant in research, the investigator will obtain the legally effective informed consent of the participant or the participant's legally authorized representative.
All investigators within RAPP will seek such consent only under circumstances that provide the prospective participant or the representative sufficient opportunity to consider whether or not to participate and minimize the possibility of coercion or undue influence.
The information given to the participant or the representative will be in language understandable to the participant or the representative. No informed consent, whether oral or written, may include any exculpatory language through which the participant or the representative is made to waive or appear to waive any of the participant's legal rights, releases or appears to release the investigator, the sponsor, the institution or its agents from liability for negligence.
An informed consent has already been used by the ORMYLIA Foundation to one of its subject groups (Annex 2).

3.3.2 Information sheet

To obtain the approval from the Ethics Committee of Matia, an Information Sheet is delivered to this committee explaining the RAPP project, the procedure of getting data, the possible risks, the way the data will be handled to ensure the data protection, with the aim of getting the approval of the Ethics Committee. The same procedure has been followed for the ORMYLIA Foundation.
Moreover, and as ORMYLIA Foundation is already in the process of its first pilot with the elderly at the Community Seniors Centre, information sheets and consent forms have been provided. An oral information and analysis of the research has been preceded and all questions have been answered to make sure that it is clear and understood by everyone. Robotics are quite a difficult subject and when addressing technology illiterates every detail has to be explained to make sure that no dark areas have remained. All participants were provided with a debriefing form and a consent form and given the time to think and decide on their participation (Annex 1 and Annex 2).

3.3.3 Ethics Committee approval

Next meeting of the Ethics Committee in Matia will be held in mid-June. At that meeting Matia researchers will present the RAPP project to the Committee and answer their members' doubts and questions in order to obtain their approval. Concerning the Ethics Committee of ORMYLIA Foundation, a meeting is arranged for late September to evaluate the first results of the project and its accordance to ethical rules. No previous meeting is needed as the Committee has already approved the research plan and official proposal. Moreover, ORMYLIA will run its test pilots in two independent institutions which are also governed by their own ethical rules and be subjected to their Ethics Committees. These institutions are: the Community Senior Centre at New Moudania of Chalkidiki and the Greek Association of Alzheimer Disease and Relative Disorders.

4. Data Protection Plan[13]

4.1 Use of personal data for research at Matia

The oral and written communication, the presentation of a clinical case or a case series and the treatment of images that refer to a subject are research activities that imply treatment of personal data, thus they are governed by the principles of the Ley de Protección de Datos de Carácter Personal 15/99 (Law for the Protection of Personal Data (LOPD 15/99)[14].

Any research or teaching activity containing data from a subject will entail previous information on the study objectives and the informed consent that LOPD 15/99 establishes. This aspect will be accomplished by a legal warning.

Law 41/2002, 14th of November, regulating the subject autonomy and his/her rights on clinical documentation and information, in its article 16 establishes "the access to the clinical file for judicial, epidemiological, public health, research or teaching purposes will be governed by what is disposed in LOPD 15/99, General Health Law 14/1986 and other regulations of applicability in each case. The access to the clinical file with these purposes forces to the preservation of the subject personal identification data separately from the clinical data, thus assuring the anonymity of the data except in the cases when the subject has given his/her consent not to separate them. The access to the documents and data of the clinical file is strictly limited to the specific purposes of each case".

As a general rule, in situations of access to data for judicial, epidemiological, public health, research or teaching purposes, anonymity should be guaranteed (this will be achieved by dissociation procedures), thus not being possible to identify the person whose data are being processed. In these cases the LOPD will not apply and the information will be treated with no need of the subject informed consent. The dissociation procedure must precede to the access to the data by the person who is going to carry out the research or teaching program.

When treating data of a person with known identity it is mandatory to have his/ her unequivocal consent even if it is for research or teaching purposes. The subject giving his/her consent has to know the purpose and the responsible of the data.

Only when this information principle is accomplished we will be legitimated for the processing of the data. Moreover, it has to be taken into account that the subject can withdraw his/her consent at any time and by any reason, data will be always available and will be deleted if the subject requires it.

In order to process health data with no assistance purposes, the clear and unequivocal statement of the subject's will that authorises us to perform the processing of data we intend to, is required.

It is convenient that all forms include the following paragraph included into a more extensive legal warning (the purpose of the data processing will be communicated to the security responsible):

> "*According to LOPD 15/99, we inform you that the personal data you provide us by filling in this form and the documentation that you may provide to Matia Instituto Gerontológico (Matia Foundation) will be included in an automatic file property of the Foundation and will only be used for management, administration and invoicing of the given services. You also expressly consent that your data be used for epidemiological, public health, teaching and research purposes.*"

[13] Handbook on European data protection law
http://www.echr.coe.int/Documents/Handbook_data_protection_ENG.pdf

[14] Spanish Law 15/1999 on Protection of Personal Data
http://www.agpd.es/portalwebAGPD/english_resources/regulations/common/pdfs/Ley_Orgaica_15-99_ingles.pdf

The most relevant articles of the Law 15/99 related to the data protection aspects of RAPP project are:

Art. 4: Quality of the data

Personal data may be collected for processing, and undergo such processing, only if they are adequate, relevant and not excessive in relation to the scope and the specified, explicit and legitimate purposes for which they were obtained.

Personal data subjected to processing may not be used for purposes incompatible with those for which they were collected. Further processing of the data for historical, statistical or scientific purposes shall not be considered incompatible.

Personal data shall be erased when they have ceased to be necessary or relevant for the purpose for which they were obtained or recorded.

They shall not be kept in a form which permits identification of the data subject for longer than necessary for the purposes for which they were obtained or recorded Personal data shall be stored in a way which permits the right of access to be exercised, unless lawfully erased.

Art. 5: Right of information in the collection of data

Research subjects from whom personal data are requested must previously be informed explicitly, precisely and unequivocally of the following:

- The existence of a file of personal data processing operation, the purpose of collecting the data, and the recipients of the information
- The obligatory or voluntary nature of replying to the questions put to them
- The consequences of obtaining the data or of refusing to provide them
- The possibility of exercising rights of access, rectification, erasure and objection
- The identity and address of the controller or of his representative, if any.

Art. 8: Data on Health

Public and private health-care institutions and centres and the corresponding professionals may process personal data relating to the health of persons consulting them or admitted to them for treatment, in accordance with the provisions of the central or regional government legislation on health care.

Art. 9: Data security

The controller or, where applicable, the processor shall adopt the technical and organisational measures necessary to ensure the security of the personal data and prevent their alteration, loss, unauthorised processing or access, having regard to the state of the art, the nature of the data stored and the risks to which they are exposed by virtue of human action or the physical or natural environment.

No personal data shall be recorded in files which do not meet the conditions laid down by rules regarding their integrity and security, as well as the rules governing the processing centres, premises, equipment, systems and programs.

Art 10: Duty of secrecy

The controller and any persons involved in any stage of processing personal data shall be subject to professional confidentiality as regards to such data and the duty to keep them. These obligations shall continue even after the end of the relations with the owner of the file, or, where applicable, the person responsible for it.

Art. 15: Right of access

The data subject shall have the right to request and obtain free of charge information on his personal data subjected to processing, on the origin of such data and on their communication or intended communication.

The information may be obtained by simply displaying the data for consultation or by indicating the data subjected to processing in writing, or in a copy, fax or photocopy, whether certified a true copy or not, in legible and intelligible form, and without using keys or codes which require the use of specific devices.

Art. 16: Right of rectification or cancellation

The controller shall be obliged to implement the right of rectification or cancellation of the data subject within a period of ten days.

4.2 Data storage and handling processes

Much research revolves around information about people –their age, lifestyle, health– drawn from records, scientific tests, surveys and interviews. Sometimes, the information also reveals facts about relatives and relationships. These types of information are sensitive and private for many people, although attitudes and expectations vary widely.
The protection of the privacy of participants is a responsibility of all people involved in research with human participants. Privacy means that the participant can control the access to personal information; he/she decides who has access to the collected data in the future.
Due to the principle of autonomy the participants have to be asked for their agreement (informed consent) before private information can be collected. It should be also ensured that all the persons involved in research work, understand and respect the requirement for confidentiality. The participants should be informed about the confidentiality policy that is used in the research.

The privacy plays a role at different levels:

- Hints to or specific personal information of any participant in publications
- It should be prevented to reveal the identity of participants in research deliberately or inadvertently, without the expressed permission of the participants.
- Dissemination of data among partners
- Access to data method of access, data formats, method of archiving (electronic and paper), including data handling, data analyses, and research communications. Offer restricted access to privacy sensitive information within the organization of the partner.
- Protection of the privacy within the organization of volunteers (employers, etc.) throughout the whole process like, communications, data exchange, presentation of findings, etc.

Furthermore the participants have to be able to control the dissemination of the collected data. The investigator is not allowed to circulate information without anonymization. This means that only relevant attributes, i.e. gender, age, etc. are retained. Another possibility is to keep the identity of the participants, but only with prior consent of those.
As already mentioned, protection of confidentiality implies informing the participants about what may be done with their data (i.e. data sharing). As databases are developed, confidentiality will become increasingly hard to maintain. Simple stripping of the participants name and its replacement with a code is no guarantee of complete confidentiality.

4.3 Process of anonymization

Information should be anonymized so that individual identities cannot be revealed. Anonymization provides a safeguard against accidental or mischievous release of confidential information. There are different ways in which personal data can be modified to conceal identities:

- Coded information contains information, which could readily identify people, but their identity is concealed by coding, the key to which is held by members of the research team using the information.
- Anonymized data with links to personal information is anonymized to the research team that holds it, but contains coded information, which could be used to identify people. The key to the code might be held by the custodians of a larger research database.
- Unlinked anonymized data contains nothing that has reasonable potential to be used by anyone to identify individuals.

As a minimum anonymized data must not contain any of the following, or codes for the following:

- Name, address, phone/fax. Number, e-mail address, full postcode.
- Any identifying reference numbers.
- Photograph or names of relatives.

Researcher and database developer should always consider – when designing studies, before passing information to others, and before publishing information-whether data contain combinations of such information that might lead to identification of individuals or very small groups. Within RAPP we will follow the unlinked anonymized data policy, excluding users having rare diseases and any other identifiers, except age, gender and nationality. Once anonymized, the data will not allow tracing back the participant in any way.
Data will be encoded, and anonymized using numerical codes. During the experiments and the development stages, the correspondence with the users list will be saved into a local database, which will be encrypted.

Annexes

Annex 1. Debriefing form

Dear ……...

Thank you very much for agreeing to participate in our study. Its main purpose is to explore training and social influences on using robots. We are going to examine whether learning how to use emails, Skype calls and social media in general (facebook, twitter etc) is easier after standard training in a classroom or by using a robot, in our case NAO from Aldebaran Robotics. We would like to study if NAO can improve social life by connecting people with friends and family faster and easier than learning how to use computers. We are going to demonstrate how easily NAO can accomplish this connection and compare it to conventional computer training. Moreover, we are going to examine if NAO, as a companion robot, can improve the psychological status of the user and have positive effect on their mood and emotions.

We are going to use a room at the Community Senior Centre to run this training. A computer lab will be organized there providing laptops that will be adjusted to the needs of the users. The robot will take part at the second phase of this training (not earlier than September 2014) but will appear for a first meeting with the users early in June. The robot is safe and easy to use.

All the data that you provide us will be kept safe and encoded in a private digital storage at ORMYLIA Foundation. Questionnaires (hard copies) will be stored in a safe private place at ORMYLIA Foundation. Codes, instead of names, are going to be used during statistical analysis. Only researcher's supervisor will have access to these data if needed.

Your participation in this research is totally voluntary and you can withdraw at any point you feel like doing this with no consequences at all. If you have agreed to provide any contact number, address or your e-mail address, in order to receive a feedback from the statistical analysis, you may expect it as soon as the results are ready. If you have some further questions, please do not hesitate to ask the researcher. Finally, we would like to let you know that your participation is highly valued, because it makes our research project possible.

Researcher: Sofia Reppou (ORMYLIA Foundation)

Supervisor: Dr. George Karagiannis (ORMYLIA Foundation)

Annex 2: Consent form

(the original was distributed in Greek language. This is a precise translation)

PARTICIPATION CONSENT SAMPLE

Research Project: **RAPP** _ Robotic Applications for Delivering Smart User Empowering Applications ***(FP7-ICT-2013-10)***

Researcher: ORMYLIA FOUNDATION

The researcher has fully explained this study to me. I have had the opportunity to ask any questions and discuss my participation. Any questions have been answered to my satisfaction.

I agree to participate in this research project, and I understand that I am free to refrain from answering any question I do not wish to answer, or to withdraw from the study completely. I have been assured that I will not be penalized in any way for withholding information or withdrawing from the study, and that nobody other than the researcher and her immediate research group will have access to the information.

I give my permission for results from the research to be used in the final report and in subsequent publication and/or presentation of results providing my identity is kept confidential.

Signature:

Name:

Date: