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INDEPENDENT LIVING**

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**CONFIDENCE**

*UBIQUITOUS CARE SYSTEM TO SUPPORT
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FOREWORD

Despite the fact that producing direct guidelines on ethical issues is a difficult task, the members of the consortium are provided with this Ethics manual. This text should contribute to our compliance with ethical standards in the research and development activities we undertake. Every individual person involved in any way in the activities of the CONFIDENCE project *must* read this manual, and every individual person joining the project at any stage *must* read this manual.

Reading this document is the minimal requirement for the project members to prove our intention to comply with the ethical assurances that the target user group of the prototype deserve. Each of us is solely responsible to incorporate this intention into our daily tasks.

The people more directly related to this workpackage, i.e., WP6, are willing to improve this document with your suggestions and are ready to assist with the ethical issues as they appear so that our older people can be cared for with the humanity, privacy and dignity that they merit.

1 INTRODUCTION

The development of the Ubiquitous Care System to Support Independent Living, from now on referred to as CONFIDENCE, follows a user-centred approach. This implies that the involvement of end-users in the research and development activities of the project is an important condition for a successful completion of the project. Additionally, user involvement throughout the project can contribute to the future adoption of the system in its commercial stage. Due to the commitment of each partner to comply with ethical principles in research with human participants, i.e., older end-users and other stakeholders, an Ethics Manual for the project is provided in this deliverable.

This document will allow each of the researchers and developers involved in the project to work with the most relevant ethical principles in mind. This will also allow facilitating a common understanding among the multifaceted researchers in the project, and a more fluent communication among the different disciplines and professions which contribute to its development when ethical, psychological, gender, and legal issues arise within the project. Moreover the needs, privacy and dignity of the older will most likely be respected with this solid ethical foundation of the project.

The main focus of the Ethics Manual will be placed on the issues more directly related to the activities of CONFIDENCE taking into account the older people as end-users and their interaction with information and communications technology (ICT). The pioneering field in which ethical guides sprung out was medicine. Other disciplines such as the social and behavioural sciences have followed. These have also provided to their associates codes of conduct and ethical guides to ensure that research with human subjects does not use the right to freedom of research beyond the rights of the participating humans. Freedom, respect for life, justice, and privacy are perhaps the most salient of the human rights contemplated in ethical guides. Most of the ethical issues related to research with human participants are well grounded. However, when technological innovations are considered, such as in CONFIDENCE, there might be issues difficult to foresee and difficult to handle. In such cases the researchers involved in the project are committed to make use of the principle of "GOOD FAITH".

Additional aims of the ethical surveillance tasks within CONFIDENCE will be to provide an understanding of how the technology incorporated in the prototype responds to the goals of maintaining independence of the older people. Additionally, it could be possible to show whether this technology provides support to this section of the population to participate in social activities. We will be able to provide social care guidelines based on relevant knowledge gained within the project. Finally, it will be possible to generalise the lessons learned from the development of the project to other ICT developments to incorporate social, ethical, and privacy issues from the formation of concepts to the deployment of the products. Systems developed with these principles in mind will certainly care for the dignity of older people and other users.

2 GENERAL ETHICAL PRINCIPLES

The meaning of some of the human rights, ethical principles, and other relevant terms appearing in legislative texts are far from being straightforward. In most cases these terms are open to interpretation within the same discipline, within the same culture, and also across cultures. This section will offer room for discussion and eventual agreement about shared understanding of these terms within the project.

2.1 Dignity

Dignity is defined as a religious ethics referring to the nature of the inalienable rights of each person that no government or person should ever be permitted to limit. Every individual that participate in CONFIDENCE as research subjects are to be handled as individuals worthy of honour and respect. The dignity of the research subjects, and the future end-users, is central for the development of the CONFIDENCE system.

2.2 Freedom

Competent individuals should be in liberty to enter into private, consensual exchange agreements of their choosing [1]. The research subjects are free to choose about the participation or discontinuation of their participation. The informed consent must be given freely by the research participant.

2.3 Integrity

From [2], different entries can be found for the term integrity. The first refers to a firm adherence to a code of especially moral values and implies trustworthiness and incorruptibility. Another meaning for integrity is the quality or state of being complete or undivided [2].

When integrity is understood in the context the EU Directive 95/46/EC, it can refer to the integrity of the data which is being processed, i.e., personal information must be relevant for the purposes for which it is to be used [3]. An organization should take reasonable steps to ensure that the data is reliable for its intended use, accurate, complete, and current. Also integrity can be understood as in the Swedish transposition of this directive, i.e., the integrity of the person [4] or the privacy of the person in terms of the EU Directive and the Finnish implementation [3], [5]. See section 3.3 for the objectives pursued by these two national acts on the processing of personal data.

2.4 Privacy

Privacy can be defined as the state in which an individual's or a group's desired level of social interaction is not exceeded. The concept of privacy also refers to the right to control other's access to one's personal world [6]. When dealing with information the principle of privacy is defined as the ability of individuals to reveal information about them selectively.

CONFIDENCE has been defined as a non-intrusive monitoring system, aiming at preserving the user's privacy. Moreover, the user will keep control on the alarm protocol and location data will only be processed with the consent of the user and for the necessary duration for the provision of a value added service. Thus, CONFIDENCE will follow [3] about the protection of

personal data and the Directive 2002/58/EC about the protection of personal data in the electronic communication sector [3], [7].

2.5 Equality

The principle of equality indicates that all individuals have the same value and status, and that all individuals should have the same legal, civil, economic and social rights [8]. The principle also includes that those rights should apply to every individual without discrimination of any kind [9].

In a research project the principle of equality is central as all research subjects must be treated as equal participants contributing to the research. This means that every participant is a valuable source for information.

2.6 Solidarity

Solidarity is the concept of an individual in a group acting in the interest of the group rather than acting in his or her own self-interest. Since the CONFIDENCE system aims at a certain target group this principle could be important. Older people form a multi-faceted group with different needs and requirements but there is a certain sense of solidarity uniting the group based on age and the increasing need for assistance from the surrounding society.

Could CONFIDENCE pose a threat to this sense of solidarity within the group of older people? We do not expect that the sense of solidarity of older people participating in the research activities is affected by this condition. However, the uptake of CONFIDENCE by actual end-users might change this situation. Despite the facts that this is an open question for which no answer is available at the moment, as researchers and developers, we will keep this issue in sight.

2.7 Citizen's rights

Respect for the individual is at the basis of the informed consent process in research with human subjects. It is also indicated in different codes of conduct for professionals. The concept of citizen's rights can be described as an ethics of politico-economy, meaning that the individual who is a formal member of a particular community is entitled to full civil rights as defined, guaranteed, and protected by the political entity [6]. At the European level the Charter of Fundamental Rights of the European Union (EU) and [3] are important parts of the political regulatory documents guaranteeing the citizens rights in the EU-member states [10] [3] CONFIDENCE will be developed according to the civil rights of the citizens including the national regulations.

2.8 Justice

Justice is often defined within the context of the legal process, as an impartial and fair settlement of conflict or differences with the imposition of proportionate punishment [6]. In a more general context the principle of justice indicates both right relationships among people and a correct social norm [8].

2.9 Safety

The definition of safety is individual to each and every person. Generally safety refers to the state of being safe and protected from physical, social, emotional, psychological or other types of failure, damage, error, danger, harm or other events which could be considered as undesirable. When considering older people safety it often refers to actions to prevent falls, diseases and fatal accidents. They often refer to the feeling of knowing that somebody will come to assistance when in problem as a feeling of safety.

CONFIDENCE proposes that the system will increase the quality of life and security of older people both indoors and outdoors and that the system will attempt to create a feeling of safety for the older people and their families and carers.

3 CONVENTIONS AND LEGISLATION RELATED TO ETHICS

Human rights have evolved rapidly during the last century. Alongside the international human right conventions, a large number of declarations and legislations have been adopted to safeguard the ethical foundation of modern society.

3.1 International conventions

3.1.1 The Nuremberg Code

The first set of official restrictions regarding research ethics principles for human experimentation, the Nuremberg Code (1947) was set during the Nuremberg trials after the Second World War. The Nuremberg Code promotes the informed consent of research participants, that the research should have positive consequences for the society and that the risks for research participants/subjects shall be reduced. The code also calls attention to the right of research participants to cancel their participation at any time [11].

3.1.2 The Declaration of Helsinki

The WORLD MEDICAL ASSOCIATION (WMA) DECLARATION OF HELSINKI: Ethical Principles for Medical Research Involving Human Subjects was adopted in June 1964 [12]. It was conceived as a statement of ethical principles to provide guidance to physicians and other participants in medical research involving human subjects. In this area, identifiable human material or identifiable personal data are part of this research field. The WMA declaration states in the 5th article that matters related to the well-being of the research subject should take precedence over the interests of science and society. The protection of life, health, privacy, and dignity of the human subject is reflected in the 10th article. The Declaration of Helsinki has been adapted to other fields of research including the psychological and social sciences [12].

3.1.3 The Belmont report

In 1974 in the United States, the National Commission for the Protection of Human Subjects of Biomedical and Behavioural Research was created. One of its missions was to identify the basic ethical principles which biomedical and behavioural research involving human subjects should follow, and to develop guidelines to assure that such research is performed in accordance with those principles. This commission identified 3 basic ethical principles: (1) respect for persons, (2) beneficence and (3) justice [13].

3.1.4 The Charter of Fundamental Rights of the European Union

A solemn declaration was provided by the EU in 2000 regarding the fundamental rights of the citizens of Europe. This aims at strengthening the protection of fundamental rights in the context of societal changes, social progress and developments in technology and science. The Charter states: “the Union is founded on the indivisible, universal values of human **dignity, freedom, equality** and **solidarity**; it is based on the principles of democracy and the rule of law. It places the individual at the heart of its activities, by establishing the citizenship of the Union and by creating an area of freedom, security and justice” (p. C 364/8) [10].

3.2 European legislation on the processing of personal data

The EU Directive 95/46/EC on the protection of individuals with regard to the processing of personal data and on the free movement of such data has been adopted or transposed into

national acts by the EU member states. This indicates that data-processing systems are designed to serve man, contribute to economic and social progress, to the expansion of trade operations, and the wellbeing of individuals while respecting the fundamental rights and freedoms of people, namely the right to privacy, irrespectively of their nationality or place of residence. The objective of this directive is that the member states protect the fundamental rights and freedoms of natural persons, and in particular their right to privacy in what concerns the processing of personal data. This directive does not apply to the processing of data performed by a natural person in activities which are exclusively personal or domestic, e.g., postal correspondence and keeping records of addresses. It does not apply either to the processing of data which has been published in the media, e.g., newspapers [3].

This directive also recognises risks to the rights of people as it may result from the use of new technologies, article 53 (p. L 281/36). The exclusion of a person from a right, benefit or a contract are mentioned as possible risks derived from the use of new technologies in data processing operations [3].

The directive on privacy and electronic communications, 2002/58/EC, was adopted in order to harmonise the provisions of the Member States required to ensure the rights and freedoms of natural persons within the processing of personal data and to ensure the free flow of personal data [7]. It applies to the processing of personal data in connection with the provision of publicly available electronic communications services in public communications networks and particularise and complement [3] within this area.

The directive indicates that the provider of a publicly available service must take appropriate measures to safeguard the security of its services. In case of particular risk of a breach of the security, the provider must inform the user of the service concerning such risk (Article 4). The confidentiality of communications shall be protected through national legislation (Article 5). Furthermore, [7] states that location data, other than traffic data, may only be processed when made anonymous, or with the consent of the users. The provider must inform the user of the type of data, the purpose and duration of the processing and whether the data will be sent to a third party for the purpose of providing the value added service (Article 9) [7].

3.2.1 Applications of the European legislation

As stated in the Description of Work of CONFIDENCE and approved by the EC, all the research conducted in the CONFIDENCE project will follow the good scientific practice guide published by the European Science Foundation (ESF) [14]. Furthermore, the system designed in CONFIDENCE project will observe the Charter of Fundamental Rights of the EU [10]. The articles of this Charter that apply directly to this project are:

- Article 1: Human dignity is inviolable. It must be respected and protected.
- Article 7: Everybody has the right to respect for his/her private and family life, home and communications.
- Article 8.1: Everybody has the right to the protection of the personal data concerning him or her.
- Article 8.2: Such data must be processed fairly for specified purposes and on the basis of the consent of the person concerned or some other legitimate basis laid down by law.
- Article 8.3: Compliance with these rules shall be subject to control by an independent authority.
- Article 25: The Union recognises and respects the rights of the elderly to lead a life of dignity and independence and to participate in social and cultural life.

CONFIDENCE aims to be a care system, which will assist elderly people to live in their own homes in a respectable way. The user will be wearing low-cost small tags, which will not interfere with his/her normal life. The design of these tags will be devised so that they do not

result humiliating to the elderly people. Our care system locates these tags using a non-intrusive positioning technique. Then, the system employs the positions of these tags to determine the situation of the user.

In summary, CONFIDENCE is committed to protect the privacy of the elderly using non-intrusive techniques.

Additionally, it will respect the dignity of the elderly people, helping them to live an independent normal life. Therefore, the objectives of this project are aligned with articles 1 and 25 of the Charter of Fundamental Rights. Articles 7 and 8 of the Charter of Fundamental Rights refer to the personal data protection. Some ethical questions concerning this issue may arise in our project. As explained before, CONFIDENCE needs information about the location of the user in the room and outdoors, to be able to detect problems. This data should be handled in a secure and confidential way, following strictly the directives established by the EU and the laws of each Member State. There, CONFIDENCE will be designed so that it follows the Directive [3] about the protection of personal data and the Directive [7] about the protection of personal data in the electronic communication sector. It will also be in compliance with the national regulations about personal data protection. Thus, the personal data will be processed under these conditions:

- **Transparency:** The user will be informed that their personal data are being processed, following the articles 10 and 11 of the directive 95/46/EC. Moreover, as stated in article 7 of the directive 95/46/EC, data will only be processed when the user has given his/her consent.
- **Legitimate purpose:** The personal data is only processed for a specified, explicit and legitimate purpose (that is, to detect abnormal events, such as falls or losses of consciousness) and will not be processed in a way incompatible with these purposes. This satisfies the article 6 of the directive 95/46/EC.
- **Proportionality:** The data will not be kept in a form which permits identification of the user for longer than is necessary (as required in article 6 of the directive 95/46/EC).
- **Security:** CONFIDENCE will implement the appropriate methods to protect personal data against unauthorised disclosure or access and against all other unlawful forms of processing (article 17 of the directive 95/46/EC). The data transmitted over the network will be encrypted (ensuring that the article 4 of the directive 2002/58/EC is complied).

Furthermore, CONFIDENCE conforms to the article 9 of the Directive 2002/58/EC, as in this system location data is only processed with the consent of the users and for the necessary duration for the provision of a value added service [3], [7].

3.3 Processing of personal data in Finland, Italy and Sweden

Transpositions of the EU Directive 95/46/EC are made at the national levels by the member states of the EU. In Finland this is the Personal Data Act (523/1999) [5]. In Sweden this transposition of the European directive is the Personal Data Act (1998:204) [4]. The Italian adoption of this directive is the Personal Data Protection Code – Legislative Decree n. 196/2003 [15].

3.3.1 The Finnish legislation

The Finnish act define its goals as the implementation, in the processing of personal data, the protection of private life and other basic rights which safeguard the right to privacy, as well as to promote the development of and compliance with good processing practice.

As indicated in [3], [4], [5], and [15], personal data processing in accord with the Finnish and other member states should be done only for defined purposes. It must be appropriate and

justified to process this data in the operations of the controller and these should be made clear to the person (See, Section 6). Notwithstanding this condition, in Section 7 — “Exclusivity of purpose” it is stated that personal data must not be used or otherwise processed in a manner incompatible with the purposes referred to in section 6. However, the later processing for purposes of historical, scientific or statistical research it is not considered incompatible with the original purposes.

3.3.2 The Swedish legislation

The Swedish Personal Data Act [4] aims at protecting people against the violation of their personal integrity. All kinds of information that is directly or indirectly referable to a natural person who is alive constitute personal data in the Swedish Personal Data Act. This means that the information about the users of the CONFIDENCE system is concerned by this act. The Personal Data Act was followed by the Personal Data Ordinance [16] which provides supplementary regulations concerning processing of personal data as mentioned in the Personal Data Act. The Personal Data Act Inquiry has made a review of the 1998 Personal Data Act in order to see if and to what extent it is possible to, within the boundaries of the EC Directive, achieve a more misuse-oriented approach [17]. Amendments to the act have been made several times since 1998, latest in 2008.

The Personal Data Act regulates *sensitive personal data* that discloses race or ethnic origin, political opinions, religious or philosophical convictions and membership of trade unions. It is also prohibited to process personal data relating to health and sexual life. The prohibition of sensitive personal data does not apply when the registered person has given *explicit consent* or when the personal data is used within health and hospital care, if it is necessary for preventive medicine, medical diagnosis, care or treatment, or the administration of health and hospital care. Health care and hospital personnel are bound to *professional secrecy* by the Swedish Secrecy Act [18].

The Swedish Personal Data Act defines *consent* as every kind of voluntary, specific and unambiguous expression of will, by which the registered person, after the receipt of information, accepts the processing of personal data concerning him/her. The registered person must, before consent is given, have received the information necessary to enable him/her to assess the advantages and disadvantages of the processing of the personal data. The consent must also be specific, which means that it must apply to a particular processing concerning the registered person that is performed by a particular controller for a particular purpose [17].

The explicit consent is a vital part of the Personal Data Act also regarding research and statistics. To strengthen the integrity of the research subject the Swedish government has appointed the Act concerning the Ethical Review of Research Involving Humans [19]. The act regulates research involving sensitive personal data according to the Personal Data Act if the research subject has not given his/her explicit consent.

3.3.3 The Italian legislation

The Italian PERSONAL DATA PROTECTION CODE [15] aims at:

- Ensuring that personal data are processed respecting data subjects' rights, fundamental freedoms and dignity, particularly with regard to confidentiality, personal identity and the right to personal data protection.
- The processing of personal data shall be regulated by affording a high level of protection for the rights and freedoms referred to in paragraph 1 in compliance with the principles of simplification, harmonisation and effectiveness of the mechanisms by which data subjects can exercise such rights and data controllers can fulfil the relevant obligations.
- Information systems and software shall be configured by minimising the use of personal data and identification data, in such a way as to rule out their processing if the purposes sought in the individual cases can be achieved by using either anonymous data or suitable arrangements to allow identifying data subjects only in cases of necessity, respectively.

In [15], it can be read that "Personal data undergoing processing shall be: a) processed lawfully and fairly; b) collected and recorded for specific, explicit and legitimate purposes and used in further processing operations in a way that is not inconsistent with said purposes; c) accurate and, when necessary, kept up to date; d) relevant, complete and not excessive in relation to the purposes for which they are collected or subsequently processed; e) kept in a form which permits identification of the data subject for no longer than is necessary for the purposes for which the data were collected or subsequently processed. Any personal data that is processed in breach of the relevant provisions concerning the processing of personal data may not be used." [15], p. 22.

4 ETHICAL ISSUES WITHIN CONFIDENCE

The user-centred approach of CONFIDENCE is essential not only because the finished product must function according to the target group's physical needs and requirements but also because the system must be ethically accepted by the user. Therefore, ethical issues will be examined and discussed within the project continuously.

One central question concerns the ownership of the information generated by the CONFIDENCE system. In this stage of the project there is no interface or transaction possible with other service providers or health services, with exception for the information sent due to an alarm situation. This means that the users themselves will be owners of the information. Whether the system is purchased by the end-user or service provider would not affect the present technical design of the system. It is possible that questions like this can change in the future but it is always important that the user *feels in charge of the system* and the information it generates.

Another question is the systems interaction and potential interference with other electronic devices present in the user's home such as pace makers and hearing aids. These kind of technical issues are of profound ethical importance since the system cannot compromise the wellbeing of the user.

The system can be used in ways that we, as researchers and developers, cannot predict or prevent. The users will likely find new ways of using the system for which it was not intended. Some of these situations may have positive, neutral, or negative consequences. Other situations may also occur that the technology cannot prevent. In these cases, only the information and instruction provided to the end-users and their own responsible behaviour can contribute to prevent potential misuses of CONFIDENCE.

In the following sections we present the most relevant principles guiding the ethical personal conduct of the professionals involved in the project. These stem from professional organisations codes and include the opinion of the European Group on Ethics (EGE).

4.1 Research and technology development

The development of new technologies within the information and communication sector front us with new difficulties and responsibilities when it comes to safeguard the privacy and freedom of the civil society. Legislations provides a foundation and the borders for ethical issues within this development, but in order to keep up with the rapid progress of the area we also need to seek guidance in ethic codes and recommendations of organisations dealing with these kind of questions on a daily basis.

4.1.1 Ethics Code of the Association for Computing Machinery

The Association for Computing Machinery (ACM) is a membership organization for computing professionals, delivering resources that advance computing as a science and a profession, situated in USA. ACM has produced a Code of Conduct that every member of the association is committed to.

Among the general moral imperatives in the ACM Code of Ethics, the respect of the privacy of others is a central ethical issue for CONFIDENCE. The Code of Ethics recognizes the responsibility of professionals to maintain the privacy and integrity of data describing individuals. This includes taking precautions to ensure the accuracy of data, protecting it from unauthorized access or accidental disclosure. Procedures must be established to allow individuals to review

their records and correct inaccuracies. Furthermore, this commitment implies that only the necessary amount of personal information is to be collected in a system, that retention and disposal periods are to be informed about clearly defined and enforced, and that personal information gathered for a specific purpose are not to be used for other purposes without the consent of the individual [[20], section 1.7].

More specific professional responsibilities include the responsibility to strive to achieve the highest quality, effectiveness and dignity in both the process and products of professional work; to know and respect existing laws pertaining to professional work; to accept and provide appropriate professional review, and to improve public understanding of computing and its consequences [[20], sections 2.1, 2.3, 2.4 and 2.7].

4.1.2 The Opinions of the European Group on Ethics

An opinion issued by the European Group on Ethics (EGE) concerning implantable ICT devices [21] seems relevant to the case of the research and development activities to be carried out within the CONFIDENCE project. In their review of commercially available implants the case of RFID chips is identified as case of an identification and location device. The group draws attention to a particular type of RFID with read-write and radio transmission capabilities. If the power source of such device could be miniaturised to become implantable, a person carrying it could be tracked anywhere. At the moment this implantable tracking RFID device does not seem possible due to the sizes of batteries. Additionally the person needs to be relatively close to a reader in order that the data stored on the chip could be accessed.

The EGE in their opinion find it difficult to provide specific rules on the use of this specific implantable technology. Therefore, they advise to follow the general principles found in EU, and national legislations in order to assess the lawfulness of these technologies. Without attempting to provide an exhaustive list of the regulations, the most relevant ones include the Charter of Fundamental Rights of the EU, the Directive on Personal data protection and its national transpositions, and the Directive [7]. The group also states that implants for non medical applications, surveillance in particular, represent a potential threat to human dignity and democracy. These applications should respect the rights of the person and the applicable legislations.

The compliance of the CONFIDENCE system with these principles and regulations has been stated above showing the sensitivity of the consortium towards protecting the dignity and other rights of the end-users. Therefore the principles of minimisation of data, specification of purpose, proportionality, and relevance [21] will be taken into account in the development activities of the project. We will strive to find the balance between the freedom of research and the rights and freedoms of the end-users.

4.2 Research involving human participants

Research involving human participants is necessary in order to gain new knowledge. Today there are ethical guidelines that put a distinct responsibility on the researcher. The researcher is responsible for the research subjects well being and for the information gathered from the research subjects. In many cases, before any research involving human participants starts a Local Ethical Committee has to approve the research process.

Typically, ethics codes for medical and psychological research are the most evolved since these scientific areas to a large extent rely on information emanating from human participants who put themselves freely at the service of scientific endeavours. We recognise the value of the participation in our research activities of many voluntaries and are honestly grateful to them.

4.2.1 Ethics Code of the American Psychological Association

The Ethical Principles of Psychologists and Code of Conduct is organised in three broad sections: the preamble, 5 general principles, and ethical standards. While the general principles aim at providing guidance to psychologists towards the highest ideals of psychology, the ethical standards are seen as enforceable rules against unethical conduct by the American Psychological Association (APA) towards its associate members. For the purpose of this ethics manual the five general principles are considered more relevant. The APA [22] indicates in this order, beneficence and non maleficence, fidelity and responsibility, integrity, justice, and respect for people's rights and dignity.

This [22] applies only to the activities of psychologists which are part of their professional role (e.g., clinical, research, educational counselling, organisational consulting, etc.). These activities may be performed throughout a variety of contexts, such as in person, postal, telephone, internet, and other electronic transmissions [22].

4.2.2 Local Ethical Committees and regulations

The local Ethical Committees of the partners of the CONFIDENCE consortium will be requested to provide approval to carry out the research activities which involve human participants. These approvals will be duly delivered to the coordinator so that the project officer receives them before those research activities are initiated.

Additionally each partner performing research involving the participation of end-users and other stake holders will follow their local regulations, namely [5], [15]-[19].

4.3 Gender issues

59% of the population in the EU aged 65 and over are women. And the proportion of women increases with age, women making up to 64% of those aged 75 and over and 71% of those of 85 and over [[23], p. 119]. Gender is an important issue when dealing with people, not only because women are expected to live longer than men but also because women and men tend to live different lives, in particular when it comes to employment, family responsibilities and education. These social differences may play an important role in shaping the individual's view on living and ageing.

Gender studies find that men have constituted the norm for humanity as a whole in many different areas. A recent Swedish report, focusing on the healthcare system and medical research, states that as a result of this, there are several risks in women not receiving the appropriate care. There is a risk that care adapted to the particular needs and preconditions if women will not be as available as care adapted to the needs of men, and that solutions, made for and tested on men, behave differently when used by women [[24], p. 11]. To avoid this discrepancy, researchers must involve women as well as men in their scientific research and deal with the eventual gender differentiating findings.

Equality between women and men is one of the fundamental principles of Community law and stated in the treaty of EU: 'the Community shall aim to eliminate inequalities and to promote equality, between men and women' [[25], Article 3 (2)]. The EU objectives on gender equality are to ensure equal opportunities and equal treatment for men and women and to combat any form of discrimination on the grounds of gender [[26], p. 7]. The method used by the EU to integrate equality between women and men into all Community policies and activities is called 'gender mainstreaming'.

The Commission endorses gender in scientific research in two dimensions: increasing female participation in science and research, and addressing gender issues associated with the subject of research. One step in this direction is the promotion of the gender perspective in all projects funded by the Commission. In the 7th Framework Programme decision it is stated that 'the integration of the gender dimension and gender equality will be addressed in all areas of research' [[27], p.8].

The CONFIDENCE system must be designed to apply to both women and men. In order to do so the research subjects are to be a balanced mixture of men and women, aiming at a 50-50 ratio of the participation of both genders. The research results can be divided into gender based groups so that conclusions can be drawn from the group as a whole and from the group of men or women separately. Similarities and differences are to be shown and discussed throughout the project.

The Ethics Manual will provide a foundation for the continuous work on implementing the two dimensions of gender within CONFIDENCE. As stated earlier, the necessities of both women and men must be addressed by the CONFIDENCE care system.

5 CONFIDENCE GUIDE TO ETHICAL CONDUCT

This section clearly separates two types of activities that are performed within the context of ICT technologies to support the independent living of older people, i.e., the CONFIDENCE project. The distinction is made not to enlarge the distances between disciplines but to promote the awareness of the proximity among them. The apparent distance between those dedicated to develop the technological components of the CONFIDENCE prototype and those more closely linked to the psychological, and social needs of the older people disappear when we realise that we are walking towards the same destination. We have a common objective. It is more likely to achieve this goal by joining the strengths of these different disciplines. This is the meaning of collaboration.

Another common compromise of each CONFIDENCE partner is the adherence to sound ethical principles in our day to day work. It seems to us that by differentiating between technology development and research with human participants we may achieve this ethical sub goal more efficiently. This is, those not directly involved in carrying out research with human participants can spare efforts in e.g. requesting ethical approvals from local ethical committees and concentrate on tasks more amenable to them.

In the brief Section 5.1 some general ethical guidelines focus on the development of technology. In the subsequent section 5.2, the area on ethics in research with human participants is dealt with in more detail.

5.1 Activities of research and technology development

In addition to the professional codes of conduct reported in section 4.1, some general ethical guidelines are provided by [28]. The guidelines considered relevant to our tasks are listed below and will be duly considered by the members of CONFIDENCE:

- We will remain knowledgeable about and apply our respective established professional/ethical codes and guidelines as appropriate;
- will proactively consider the intended uses and impacts of our specific technologies, as well as the potential for accidental use, misuse, and abuse;
- will provide, to the reasonably possible extent, inherent safety features to maximize the prevention of accidents, misuse, and abuse;
- will proactively initiate ethical discussions among ourselves and support these as technologies develop;
- will provide human research subjects with a clear understanding of the personal information acquired and how it will be stored, analyzed, and applied; and,
- will responsibly handle any personal information obtained from research subjects [28].

5.2 Activities of research involving human participants

5.2.1 Informed consent

Whether a person can exercise the right of freedom, in our case, the right to choose freely to participate in a research activity or not, or to use the CONFIDENCE system, depends on the information which is provided before the person makes a decision. The amount of information, its accuracy, comprehensibility, etc., might affect this right to a certain degree. Scientific research tries to assure the freedom of choice of the research subject through the informed consent. The informed consent can be described as a process in which the risks, benefits, and requirements of a research activity are explained using a language which can be understood by

volunteer participants. The research activity with the participant should begin only after the participant has reviewed, understood, and signed this informed consent. As a process, written or verbal information exchanged with any potential voluntary participant in relation to their participation can be considered part of the informed consent obtained from the research subjects.

5.3 Request for opinions from ethical committees

The Local Ethical Committees of the organisations involved in the research activities in question should be requested for opinions or comment if the realization of the research requires it. Such research projects can be those whose realization can cause physical or psychological harm to the subjects/participants or endanger their legal protection. Also, a request for comment should be formulated when the funding organisation requires ethical clearance for the development of the research activities covered by this funding. A general principle is that a comment should be requested for experimental research designs and especially for postgraduate studies and extensive research projects of the departments or institutes.

The ethical committees may require the following documents as the basis of their statement:

1. A covering letter (including the reasons for the request)
2. A summary of the research plan (maybe in the native language, if English or another foreign language is used in the research project)
3. The research plan, including
 - other material given to the subjects/participants (diaries, questionnaires etc.)
 - a disquisition of how the consent of the subjects/participants for participation is acquired
 - an evaluation by the researcher/the person responsible for the project of the ethicality of the project
4. Information handout and notice of consent for the subjects/participants
5. Description of the scientific research data file

The instructions of the Ethical Committee of the University of Jyväskylä on what the information sheet handed to the subjects/participants should include represent a guideline within CONFIDENCE. The information sheet should include the following:

1. Contact information of the researchers and the researcher responsible for the project
2. Background information on the project to the appropriate extent: research institute(s) and support organizations or -groups
3. Storing of research data
4. Purpose, objective and significance of the research project
5. Procedures the subjects/participants will face
6. Advantages and disadvantages the subjects/participants can expect within reasonable limits; especially the possible strains or health risks caused by the research to the subjects/participants and their probability
7. How and for what purposes the acquired information is used
8. Rights of the subjects/participants: that they can refuse to participate in the research, that they can in any phase ask additional information on the research, and that they can cancel their participation in the research in any phase
9. Whether the subjects/participants are insured on behalf of the research project or if it is assumed that they participate on the basis of their personal insurances
10. Consent of the subject/participant or her/his guardian/legal representative of participating in the research

If the participant is minor, consent must be requested from her or his guardian or legal representative. If the subject/participant is not able to give consent because of a mental disturbance, mental disability or other corresponding reason, it must be requested from the guardian or legal representative of the subject/participant. The notice of consent is attached to the request for comment. Alternatively, if the participant is not able to give consent he/she may be excused from participation.

5.4 Management of incidental findings

Incidental findings are considered those which occasionally arise unexpectedly in the course of a research and are unrelated to its original purpose. These may have significance for the health or well-being of the research subject. Often, incidental findings are associated to biomedical research but can appear in other fields as well. The management plan to deal with incidental findings must be included in those research activities in which the researchers can believe that incidental findings are possible.

In drafting this section we clearly commit ourselves to follow the recommendation provided in the Ethics Review 7FP, Consensus Report Form. This report is included in the Appendix.

The text presented below is the first attempt to elaborate the management plan to deal with incidental findings within the project CONFIDENCE. Discussions within the consortium may alter the content of this management plan. In addition to the internal discussions of the consortium other sources such as the European Commission (EC), other projects' experiences, the EGE group, and other colleagues involved in similar duties, will be contrasted in order to ratify or to improve this management plan.

5.4.1 Management plan

This research is done to investigate the needs of the potential users of CONFIDENCE, or to establish the requirements of the users, to obtain data relative to the movement of the limbs and body to develop the interpretation subsystem of CONFIDENCE whose function is to detect falls for example, or to evaluate the usability of the system's prototype.

This research is not designed to examine your physical condition or functional ability. This is not a medical examination nor does it substitute the examination of a physician/medical professional that you could order for yourself if you have a health problem.

However, if the researchers believe that there may be a problem that could deserve medical attention you have the right to be informed about it or not to be informed at all. It is possible that you could be unnecessarily worried if a problem were suspected, but not actually found in a medical examination.

The information generated in this research is anonymous and will not be disclosed to any other social, health, or insurance organisation, or any other person outside this research project.

We would like to ask what you would like us to do if we believe that a problem may exist, PLEASE, mark the box which applies to your choice:

YES, I would like to be informed about the existence of a potential health problem,

NO, I would not like to be informed about the existence of a potential health problem.

If you answered YES, after the researcher informs you about this potential problem, it is your responsibility to seek medical consultation about it. We may be able to provide you with more detailed information about this problem if you wish.

If you do not answer YES or NO to this previous question, as researchers, and solely in your own interest, we may consult for medical advice preserving your anonymity, and eventually may inform YOU about this potential problem.

6 POTENTIAL SCENARIOS OF MISUSE OF CONFIDENCE

As [29] indicates, the current RFID standard allows for the unique identification of every individual item to which an RFID tag is attached. In the case of CONFIDENCE, each body part and the person as a whole, we can imagine, can be identified similarly. The ethical issue of privacy comes to the forefront in this respect. Some of the entries included below deal with this issue indicating that in any of these scenarios the privacy of the end-users might be jeopardized. Furthermore, privacy is perhaps the most cited ethical issue addressed and reported in the scientific literature reviewed thus far.

6.1 Disclosure of users' information without consent

A) *Scenario:* The physician/caregiver of Person, who is a user of CONFIDENCE, finds some problem related to the ability of this Person to carry out a particular activity of daily living and considers that the partner of Person needs to know about this. However, Person does not know that this can happen, or does not want this information to be disclosed to others.

Preventive countermeasures: At this stage, this situation is not likely to occur because the CONFIDENCE prototype does not consider transmitting the data to health or care services. However, future applications of the concept may contemplate this feature. In this case possible countermeasures include informing the end-user with certain periodicity of this issue, when the system is adopted, during its set up, and while it is in use. Whether this should be a technical requirement or providing printed information to the user would suffice is a question open to debate.

B) *Scenario:* Data are sometimes sent over to an external service provider for instance to send an alarm. Sent data can be just the ones needed for the rescue of the person (for instance the location if the user is outdoors) or medical relevant data to be analysed to provide a better care. In both cases data can be classified as sensible. Gaining access to the single communication of alarms (i.e. cracking into one local system) or to the central system may lead to a not consented usage of the information.

Preventive countermeasures: Alarm data are never containing personal data but just identifiers. Using this identifier the carer can locally access also the personal data. Data are always sent through encrypted channels.

C) *Scenario:* Data are stored locally but someone gains access to the system and its data.

Preventive countermeasures: To avoid that other people get hold of the information, the system can be protected by a personal log in or other identification procedure. The information is encrypted.

6.2 Insurance companies

Scenario: A person obtains certain disability pension from the social services, health care, or private insurance. Due to the information provided by CONFIDENCE (disclosed or obtained by other means) the disability pension is reduced or cancelled totally. The information might not be totally accurate, can be misinterpreted, in such a way that might lead an inspector to believe that the person is not disabled at the level at which the pension was granted but the condition has improved. For instance, after starting to use CONFIDENCE, this person goes out with other people more often.

Preventive countermeasures: At the present moment the information obtained by the system is stored locally and not attainable by external organisations or persons. In the future this scenario may be prevented by providing information and instruction to the user and through agreements between the user and the insurance provider on how to use the information provided by the system.

6.3 Information beyond the intended or announced use of RFID

Scenario: The following case [30] was obtained from the response to the EU RFID consultation: “Here in Scotland, the government offers concessionary, or free, bus passes to old age pensioners (OAPs). In April of 2005, the old bus pass was replaced by an attractive wallet-sized plastic card with photo identification. During the application process for the new card, pensioners were advised that all local council benefits, if any, could be attached to this card (for which there was an ‘opt out’ option) and that plans called for National Health Service (NHS) records to be attached in future as well” ... later “on 9 April 2005, the Sunday Herald reported that Scotland’s government ... allegedly had far-reaching plans to attach all manner of data to these bus passes, including linking citizen entitlement cards with address-based data (Scottish Executive’s Geographic Information Services [Segis] report) in a programme ironically identified as Customer First. Thus, the £35 million microchipped card and database system being adopted by all 32 Scottish councils to streamline access to services would consolidate databases concerning forestry, the environment, policing, health and land ownership, as well as link to the Scottish Neighbourhood Statistics (SNS) database, which compiles lifestyle indicators for every postcode area, county and constituency of Scotland. All of this, just to ride the bus for free.” ... “a clear case of **forcing** RFID technology onto the old, the vulnerable, the least likely to notice or complain [30].”

Preventive countermeasures: At a conception or design stage of the system plan define the purposes the system will fulfil. If necessary, implement the means to preclude possible extensions of its functions without the consent of the user. Inform the user about each of the implications of using the technology if these are already considered. There is always the possibility to abandon the use of the system or to “fry the chips”.

6.4 Burglary

Scenario: The person using the CONFIDENCE system usually takes a long walk outside between 10 pm and 11 pm. Due to the information stored in the system an intruder can get hold of this information and the position of the user and commit a burglary when the user is not at home.

Preventive countermeasures: Alarm data do not contain personal data but just identifiers. Using these identifiers the people that have access to the information can access the personal data locally without risking intruders to identify the person who generates the information. Data are always sent through encrypted channels.

6.5 Social care services

Scenario: A person obtains social care services based on assessments of his/her physical abilities and over all health. With information from the CONFIDENCE system (disclosed or obtained by other means) the social care provider may decide to reduce the services or make other changes that affect the user negatively. The information may not be totally accurate and can be misinterpreted in a way that may lead the inspector to think that the user is more active than stated in the assessment made by the social care services.

Preventive countermeasures: The information provided by the CONFIDENCE system belongs exclusively to the user and a social care service provider is not entitled to get hold of this information without the consent of the user. If a user agrees to provide the social care services with the information from the CONFIDENCE system there should be an explicit agreement on how to deal with these kinds of findings between the user and the social care service provider.

6.6 Health services

Scenario: A physician that has access to a person's information through the CONFIDENCE system uses the information to do general research without the user's consent.

Preventive countermeasures: An agreement should be set between the user and whoever other person/health care or social care provider that gains access to the user's information. This agreement should deal with these kinds of questions and set explicit rules for the usage of the information.

6.7 Family relations

Scenario: A person that uses the CONFIDENCE system has relatives or a partner that use the information provided by the system to control or supervise the user against his/her will. This is a scenario where pre-existing family or partner power relations can take new ways of controlling the user as the information about the user exposes the users' everyday life to his/her partner/family etc.

Preventive countermeasures: The information provided by the CONFIDENCE system belongs solely to the user. To avoid that other people get hold of this information the system can be protected by a personal log in or other identification procedure.

6.8 Participation in social activities

Scenario: A person using the CONFIDENCE system is active in different kinds of social activities. A company/organisation/public authority uses the information from the system in order to profile the user's interests, social network, religious beliefs etc.

Preventive countermeasures: Information from the system is encrypted and all measures are taken so that the information can not be spread to unauthorized persons/organisations.

6.9 When the technology cannot prevent misuse

There are potential scenarios of misuse, identified and unidentified, that can not be prevented by the technology.

A) *Scenario:* In an attempt to experiment or to help another person, a current user of CONFIDENCE system transfers or lends the system to another person without resetting the system. This may generate "abnormal" values in the system and raise an alarm.

B) *Scenario:* For unpredictable reasons, a user of CONFIDENCE provides the access password, identification code, or other keys to access and use the system to a close relative or friend.

There will be situations which go beyond the capacity of the technology to prevent misuse if the users are not aware of the risks involved or do not lend enough credit to the advice of the provider to safeguard their own privacy. Furthermore, the users will likely find new uses for which the system was not conceived. These cases might be positive, neutral or negative. The technology itself might not be able to cope with and prevent each of these scenarios when the users operate the system in their own ways. To prevent situations like this the only precaution possible in this stage is to make sure that the user is properly informed about the function of the system.

7 SCIENTIFIC REVIEW OF ETHICAL ISSUES IN ICT

Several bibliographic databases have been queried with keywords and keyword combinations providing numerous references, most of these were not judged useful and were excluded from further considerations. Many ethical issues are discussed but often they are not taken as the focus of the research. The ethics of our conduct against the potential end-users are of up most importance to make this project a success. The following scientific references have been taken into account to support the purposes of the Ethical Manual of CONFIDENCE. These are summarised below and will be integrated later into the manual itself.

1- An enquiry into the ethical efficacy of the use of radio frequency identification technology [31]: This paper provides an in-depth analysis of the privacy rights dilemma surrounding radio frequency identification (RFID) technology. As one example of ubiquitous information system, RFID has multitudinous applications in various industries and businesses across society. The use of this technology will have to lead to a policy setting dilemma in that a balance between individuals' privacy concerns and the benefits that they derive from it must be drawn. After describing the basic RFID technology and some of its most prevalent uses, a definition of privacy is derived in the context of information systems. To illustrate current attempts at controlling the undesirable side effects of RFID, Lessig's cyberspace framework is presented. It is found that each of Lessig's components is inadequate at preventing individual privacy violations in RFID. The main focus within this framework is on the norms of society. The social norm mechanism that addresses privacy issues in cyberspace is the Fair Information Practices Principles (FIPP). After an analysis of these principles, it is posited that the FIPP only deal with procedural justice issues related to data collection and omit distributive and interactional justice reasoning related to the actual beneficial and detrimental outcomes to the individuals from whom data is obtained. Thus, RFID is presented in the context of the tension between the many benefits that are provided by the technology in social exchanges, and the risk it carries of the loss of privacy. The new, expanded framework recognizes both sides of the issue with the ultimate goal of providing a greater understanding of how privacy issues can be addressed with RFID technology [31].

2- Do Ethical Guidelines Give Guidance? A Critical Examination of Eight Ethics Regulations: Eriksson, Höglund, and Helgesson [32] indicate that the number of legal and non-legal ethical regulations in the biomedical field has increased tremendously, leaving present-day practitioners and researchers in a virtual crossfire of legislations and guidelines. Judging by the production and by the way these regulations are motivated and presented, they are held to be of great importance to ethical practice. This paper questions the premise that laws and ethical guidelines are as useful for ethical decision making as is often assumed. However, this has had little effect on the practice of guideline production. A number of difficulties in applying the directives of ethical regulations in practical situations have been identified. Three major kinds of problems are the interpretation problem, the multiplicity problem, and the legalization problem. These problems concern what can actually be attained by rules, the multiplicity of regulations and values, and the present-day tendency to treat ethics as a quasi-legal endeavour. A number of ethical regulations are reviewed to establish to what extent such difficulties are encountered. Informed consent is a central and much discussed theme in bioethics, and it is also an important and well-established topic in most ethical guidelines. If ethical regulations are action guiding at all, they can be expected to be so regarding informed consent. The authors aim at analysing a variety of ethical guidelines with respect to their treatment of informed consent to find out to what extent they face the three problems listed, and what is the role of these guidelines. [32] argue that the content of ethical guidelines is too meagre to be action guiding, that the multitude of guidelines and regulations adds to the interpretational problems, and that an increase in legal regulations results in an unfortunate change in how ethics are perceived.

3- A Systematic Review of Practice Standards and Research Ethics in Technology-Based Home Health Care Intervention Programs for Older Adults [33]: This review assesses frequencies of reporting adherence to professional practice standards and research ethics in studies of technology-based home health care programs. Databases were searched to yield 2,866 abstracts that were independently rated by two reviewers using inclusion-exclusion criteria, resulting in 107 articles that were then reviewed for reports of practice standards and research ethics. The results indicate that the issues related to professional practice standards and research ethics were inadequately reported. When reported, adherence to practice standards included preintervention training, use of intervention protocols, supervision, and mechanisms for risk management. Research ethics most commonly reported were informed consents, ethics review boards approval, and protection of privacy. The authors conclude that the results raise questions as to whether practice standards and research ethics are addressed sufficiently when health service delivery occurs in technology based environments. In e-health service delivery, guidelines for professional reference are needed.

4- The diffusion of virtual communities in health care: Concepts and challenges [34]: This article provides an overview and discussion of virtual communities in health care discussing ethical, legal and technical considerations. Medical and social science literature including survey studies, randomized and non-randomized controlled interventions and reviews were compiled. The results indicate that a virtual community in health care as a group of people using telecommunication with the purposes of delivering health care and education covers a wide range of clinical specialties, technologies and stakeholders. A number of issues are discussed including ethical challenges, the concepts of identity and deception, privacy and confidentiality and technical issues, such as sociability and usability. To conclude the authors argue that virtual communities may empower patients and enhance coordination of care services. However, there is not sufficient evidence of the effectiveness of virtual communities on clinical outcomes or patient empowerment. They also note that when practitioners utilize virtual community tools to communicate with patients or colleagues they have to maximize sociability and usability of this mode of communication, while addressing concerns for privacy and the fear of de-humanizing practice, and the lack of clarity or relevance of current legislative frameworks.

5- Chips, tags and scanners: Ethical challenges for radio frequency identification [35]: Radio Frequency Identification (RFID) systems identify and track objects, animals and, in principle, people. The ability to gather information obtained by tracking consumer goods, government documents, monetary transactions and human beings raises a number of interesting and important privacy issues. Moreover, RFID systems pose an ensemble of other ethical challenges related to appropriate uses and users of such systems. This paper reviews a number of RFID applications with the intention of identifying the technology's benefits and possible misuses. Offers an overview and discussion of the most important ethical issues concerning RFID, and examines some methods of protecting privacy which could be useful for the development of CONFIDENCE.

6- The duality in using information and communication technology in elder care [36]: This paper reports a study showing values and perceptions held by professional carers of older people about the use of information and communication technology applications. Besides different technical barriers and the presumed negative attitudes among older people, personnel values and attitudes have been found to be an important cause of resistance to change and slowness in introducing information and communication technology in health care of older people. An interview study was conducted in 2004 with 10 healthcare personnel with 3–26 years experience of working in home care and nursing homes in Northern Sweden. The interpretation of values and perceptions among carers revealed a duality where the carers perceived information and communication technology as a promoter of both inhumane and humane care. This duality seemed to make them defensive and resistant to change. Within the overall duality,

other dualities were embedded that described both perceptions about the care of older people and about being a carer. There was evidence of resistance among professional carers towards an introduction of information and communication technology applications in elder care. Carers considered that the same attributes of information and communication technology that could promote humane care could also lead to dehumanized care. The authors propose the introduction of ethical discussions when introducing information and communication technology applications in elder care. The best alternative for all those concerned should be considered. It should promote aspects of wellbeing and dignity, and fears of inhumane care among carers must be discussed.

7- Designing databases that enhance people's privacy without hindering organizations: Towards informational self-determination [37]: The authors argue that future database systems must provide autonomy for individuals for the privacy of data they manage. They propose a design for such a system, identify challenges and problems, and suggest some approaches to these. The reasons for informational self-determination systems are elaborated, including legal, organizational and technical issues. The purpose is to achieve a widely-accepted realistic and practical solution in order to ensure privacy for individuals in our future world without degrading business potential and security.

8- Strategies for engineering development: Advancing technology, prioritising people [38]: At its best, engineering changes the world for the benefit of humanity. In some instances, appropriate technology is available but is not being applied, such as in water treatment. In other instances, inappropriate technology is being developed and applied, such as cluster munitions. These instances reflect a tendency for engineering, as presently taught and practised, to prioritise technical ingenuity over helping people. Engineering priorities are usually defined using technical systems approaches based on a calculation of consequences. In instances where engineers explicitly consider the ethics of their activities they most often base their analysis on utilitarianism or contractualism. These are important approaches, but they have significant limitations. In particular, they neglect the human factor, our responsibilities in relation to others as persons. The ways in which these responsibilities have been expressed by philosophers are explored. The author proposes a new attitude that every engineer could adopt in applying his or her technical skills: "*Here I am, how can I help you?*"

9- Personal emergency alarms: What impact do they have on older people's lives? [39]: This study attempts to determine if, how often and in what types of situations older people use personal alarms and to explore the impact of personal alarm technology on older people's lives. The research was retrospective and involved a mail survey to 2610 users of the Silver Chain CareLink Personal Alarm Service. The results showed that clients wear their alarm consistently around their home and in the garden; however, use is low in the shower/bath and in bed at night. Clients reported positive impacts by gaining faster assistance in an emergency, extending the time they are able to remain living at home, increasing their sense of security, reducing anxiety about falling and increasing confidence in performing everyday activities. It is concluded that personal alarms have many positive impacts on the lives of older people.

10- Ambient intelligence, ethics and privacy [40]: Networked and ubiquitous information and communication technologies (ICTs) and ambient intelligence are increasingly used in the home environment to facilitate independent living for older adults. These systems collect and disperse a high volume of personal data, which is used for assistance and monitoring by professional carers in order to provide more responsive care for high-risk individuals. These personal data are often also sent to commercial service providers. The computerization of the home environments, while providing many positive potential uses, goes together with concerns about privacy, sensitivity of data, ethics, and the inclusion of all groups of older adults, also those with dementia. It is arguable that present privacy regulation lags behind technological developments, especially with society moving into the era of ambient intelligence, which promises to intensify

data collection in kind, frequency and volume. Also, personal control by older users is becoming ever more laborious to exercise in ambient intelligence environments. A combined agenda of technological and legislative developments is needed to support, as well as inform, the wider public and especially the older population about the legitimacy and the appropriateness of the data collection for the service provided. While principles hold just as much for the internet domain as for ambient intelligence, the complexity and diversity of the latter call for extra care to ensure transparency for the older population. In this context, ease of use, simplicity, little interaction demanded might work against the transparency or educated consent of use of older people. This may be an issue to deal with in CONFIDENCE.

11- eHealth services and technology: Challenges for co-development [41]: The promises of ICT have been poorly redeemed in health care; many projects have failed. This article conceptualizes the co-construction of services and technologies in order to help future practitioners in the field to understand and find solutions to the challenges in ICT-enhanced service change. Structuring the findings of a case study with the help of theoretical concepts was used for conceptualization. The conceptualization then is applied in another case to study its potential for finding challenges and suggesting solutions. Both cases demonstrate challenges for co-development that contributed to poor project outcomes. Participants in e-health projects need a better understanding of development as the parallel shaping of multiple objects. They need better skills in managing the change process and a better understanding of methods for collaboration throughout the development. The projects would benefit from networking with actors who have adequate understanding of the process as a whole and of methods of co-development.

12- Ethical issues in participatory action research [42]: This study describes the ethical issues arising in participatory action research (PAR), on the basis of both an empirical study and the research literature, and to discuss how to deal with these issues. The data consist of the experiences and results of three phases of PAR relating to orthopaedic patients with rheumatoid arthritis and the analysis of 20 articles on the ethics of action research. As a result, the following ethical issues and the ways to treat them were discussed: informed consent, confidentiality and anonymity, protecting an individual from harm, the role of the researcher, the location of 'power' in PAR, and the ownership of the research. The flexibility of PAR in use and its main features are also related to the decisions made and actions taken in response to ethical issues. It is particularly important in PAR to proceed according to the participants, and to involve them from the beginning of the process.

13- Independent living, technology and ethics [43]: The authors propose that developing self-legislative ethical guidance documents to inform the research and development of enabling technologies for older persons and disabled persons is a worthwhile pursuit. The basis of the discussion is an argument from analogy between clinical medical research and enabling technology research. Similarities between clinical medical research and development of enabling technology research and development are that trial participation does not equal benefit to participants, informed consent can be problematic, participants may incur costs, participation can be risky, situation of participants after the trial is uncertain, the privacy of participant data is of central importance, user groups with special needs as participants are involved, raising unfounded expectations is a concern, and that ethics committees are relevant in designing studies. Despite these parallels, the ethical guidelines for clinical medical research cannot as such be implemented to the multiprofessional and multidisciplinary field of enabling technology research and development. As the search for technological solutions for the support of independent living of older and disabled persons has become a source of increasing attention in recent years, ethical issues have been emerging especially through the implementation of information and communication technology for new and often vulnerable user groups. Some of the main ethical issues in enabling technology include the surveillance of persons and the accumulation of personal information in new types of databases. In developing ethical

guidelines for this growing field of enabling technology development, the role of international professional organizations is crucial.

14- Information ethics and the law of data representations [44]: A central concept in this paper is the information entity. It is considered as an autonomous information object inhabiting an infosphere comprising both tangible and intangible informational patterns. Information law, including the law of privacy and of intellectual property, is especially likely to benefit from a coherent and comprehensive theory of information ethics. How information ethics might apply to legal doctrine is illustrated by examining legal questions related to the ownership and control of the personal data representations. These may consist of photographs, and consumer profiles, that have become ubiquitous with the proliferation of information and communication technologies. Such data representations will in many instances constitute the kind of personal data that information ethics asserts constitutes an information entity. The legal doctrine remains partly inoperative as to which data might constitute a given information entity in a given case. Information ethics, in its current state of development, is not entirely helpful in answering this critical question. The author concludes that while information ethics holds some promise to bring coherence to this area of the law, the articulation of a richer theory of information ethics will be necessary before this promise becomes a fact. Despite the strong theoretical content, issues concerning the ownership of the data might be useful in the development of this project.

15- Discovery and disclosure of incidental findings in neuroimaging research [45]: The authors carried out a web-based survey to investigate different protocols for handling incidental findings on brain research magnetic resonance imaging (MRI) studies, and provide a platform for establishing formal discussions of related ethical and policy issues. In the survey they asked questions regarding knowledge and handling of incidental findings, as well as characteristics of the scanning environment, training required, Institutional Review Board (IRB) protocol requirements, and the involvement of a neuroradiologist. The results show that 82 % of the respondents reported discovering incidental findings in their studies, such as arteriovenous malformations, brain tumours, and developmental abnormalities. However, there was great variability in the procedures for handling and communicating incidental findings to subjects, the role of the neuroradiologist, personnel permitted to operate equipment, and their training. The authors conclude that guidelines are needed for improved standards for detecting and communicating incidental findings on brain MRI research. Despite the focus on MRI, the contents of the study might provide some useful information for the development of the management plan of incidental findings within CONFIDENCE.

16- Radio Frequency Identification and the Ethics of Privacy [29]: This article reports on a rapidly emerging technology, radio frequency identification (RFID) tags on which CONFIDENCE relies, and discusses some of the implications of this new technology for the ethics of privacy. This paper concludes that the ethics of privacy is an important and largely unexplored topic for business managers. The topic is particularly pressing given RFID and other emerging technologies that have the potential to challenge society's ethical beliefs. It is time for managers to purposefully incorporate discussion of the ethics of privacy into their portfolio of strategy dimensions, and to more carefully include privacy in planning analyses. A final aim of the authors is to initiate a discussion on privacy and set a basis for managerial decision making. A question to be considered by the CONFIDENCE partners is that privacy should be considered in the analysis, design, and development of the technical components of the system beyond compliance with, e.g., the EC Personal Data Processing directive.

17- Socially dependable design: The challenge of ageing populations for HCI [46]: This paper focuses on the needs of an ageing population and the implications for Human Computer Interaction (HCI) research. The authors argue that a shift needs to be done, from a medically oriented focus on security towards a user-centred focus on quality of life. A better understanding of our need for human contact and how different communications technologies might best

support that need will improve the quality of life of many isolated older people. To make the technology attractive, provide privacy, allow informed choice and reduce the isolation the development needs to approach a socially dependent system design. Socially dependable systems take account of social context, the need for sociability and the principle of open access for all. With the justification of not wanting their homes looking like a clinic or a hospital, many elderly reject installation of telecare monitoring technology. The authors suggest taking more attention to aesthetic design to make the technology attractive. Another suggestion is to develop a system with the possibility of providing additional functions. Consequently, the technology could be introduced to the user at an earlier state, allowing the user to get familiar with the system and making it more mainstream. Mentioned problems when introducing a technical system (such as the emergency alarm button) are that the user is in denial of being in need of a safety system and that the user do not comply using it properly. In order to reduce these risks new technology, that allow monitoring without the user actually noticing it, are now on the market. These kinds of systems provide a new set of problems including issues concerning privacy, acceptability and the user's right to make an informed choice. The authors suggest that a user-centred approach would focus on these problems in designing the technical system. What, if any, raw activity data goes out of the house? When an inference is drawn from activity data, are the users aware this inference has been drawn and who it has been communicated to? How are the automated inferences from sensors presented and acted upon outside of the home? The later questions also leads to a discussion about responsibility for false inference – are the system or the user responsible for the data going out of the users home? Another question is how we can ensure that the availability of new technological solutions does not increase isolation? According to the authors, some elderly use the emergency alarm button to call for attention when not actually being in need of help. In one aspect this is a false alarm but on the other hand it is a call for reassurance and confirmation. When it comes to costs, access and provision, the authors state that the social class is crucial. Class is an important indicator of whether an older person's needs are likely to be met. Further more, a person working may not be able to check on her/his relative on a daily basis. If the technical solution is expensive it may only be available to people with money. Access to all is hence a crucial element of the socially dependable system. A broader conceptualisation of the term 'inclusive', which takes into account not just different physical ability but also different socioeconomic power, is therefore needed not to exclude people from technology due to economic situation.

18- Traces of value of computerization – effects of IT in elderly care

Original Swedish title: "Spår av datoriseringens värden – effekter av IT i äldreomsorgen" [47]: The objective of this academic dissertation is to develop knowledge about the values of computerization. This is done by analysing and creating understanding of the reasons for computerization, and the effects of computerization on a personal as well as work related level. This is done studying four administrative and elderly care supporting IT systems in three municipalities in Sweden. The author defines four value areas relating to the computerization of elderly care; Management values, integration values, care values and professional values. Each value derives from the anticipated and experienced effects of computerization by different actor groups. A total of seven actor groups (such as system owners, administrators, political management, and care professionals) are identified. The dissertation concludes that experience and traditional values as well as existing IT systems have a strong influence on the computerization process. The author also suggests that development of an IT system for elderly care should be done through dialogue and with different types of concretisations of the future use of the system. Furthermore it is important to integrate work tasks and tools in order to ensure that the IT system is seen as a support. IT systems can, in elderly care, be described as a symbol for administration or as a symbol for the modern society. Finally, IT systems and management values are prerequisites for realization of care values. It also discusses the guidelines the Swedish Research Council's ethical principles for research in the humanities and social sciences. The guidelines include the right to get proper information about the research; the mutual consent to participate; the requirement of confidentiality and the demand for usage of

the data in scientific purposes only. The guidelines also include two recommendations: to let the interviewed read particularly delicate phrases before publication, and to inform the person where the results will be published.

19- E-Health in health and social care of elderly - Technology, ethics and practical knowledge
Original Swedish title: E-hälsa i vård och omsorg av äldre. Teknik, etik och praktik. [48]: This publication aims to highlight the possibilities and difficulties that emerge when ICT is used in the care of elderly. The publication is primarily written for students and professionals involved in care of elderly. Throughout the book there are three different approaches carried out by the three authors: the theoretical scientist, the practical scientist and the narrator conveying the experience of the interviewees. Preferably the publication can be used for discussions and it includes interesting reflections regarding social context and ethics. The authors state that technology can overcome distance to health care services and relatives, facilitate communications and increase safety. It can also increase accessibility and the sense of freedom for the elderly. Identified problems include issues concerning privacy and integrity, changes in relations when communication is done by the use of technical devices and the concern that the social and health care services will be “dehumanized” and hence compromising individual dignity of the elderly. The authors highlight the particular problems concerning people with dementia, when the capacity to understand and to communicate is limited. This means that other people have to make sure that the needs of the person are being met. In order to be able to ethically make these decisions, knowledge, humility, and empathy are needed. The development of equipping the home environment of elderly with advanced assistive technology brings on a responsibility of *what* is being done, *why* and in *which way*. It is therefore crucial to include the knowledge and understanding of the surroundings and social context where the assistive technology is used.

20- IT in care services - Performer's expected effects of an IT-system in the care services of elderly and persons with functional disabilities

Original Swedish title: IT inom omsorgen – Förväntade effekter av införande av IT-system för utförarna inom äldre- och handikappomsorgen [49]: This publication is a report done jointly with a local project in Sweden – IT in care services (“IT inom omsorgen”). The project aimed to computerize the documentation of the care services in the municipality of Stockholm and was primarily focused on the performers of the care services, not the elderly. This report is based on interviews with central actors in the project, including employees and heads of the elderly care services. The main contribution of this report, in the context of CONFIDENCE, is the knowledge that a massive project can be jeopardized if the project management and the persons doing the practical work are not in tune with each other.

21- Health care for the elderly - Two cases of technology diffusion [50]: This paper is written by three authors associated with the Department of Economics and the Lund University Centre for Health Economics and the focus of the paper is on the economic effects of medical technology. Findings show that applications of new medical technology often is restricted to individuals within a certain age-span, as the criteria for treating patients gradually widens, younger and/or older patients will be included as well. In order to analyse this kind of diffusion of medical technology, two cases are studied: coronary bypass surgery and renal dialysis. The authors conclude that the diffusion of technology to elderly patients could have a noticeable effect on per capita health care expenditures among the oldest elderly. This paper does not have any obvious connection to the CONFIDENCE project, but the paper raises some interesting questions about how and why technology are introduced within the field of health care. Who is the technology made for? What about CONFIDENCE when it comes to the economic aspect, with regards to expenditures increasing with the age of the user?

22- Telecare of frail elderly - Reflections and experience among health personnel and family members [51]: The overall aim of the research project is to illuminate reasoning and

experiences of using applications of telecare for frail elderly persons. The research project was set up to provide additional knowledge on some of the important questions regarding quality and implementation aspects of the use of ICT. The academic dissertation focuses on ICT solutions used for communication between elderly and the health care services/family members. The findings of this research project are therefore of limited interest for the CONFIDENCE solution. However, some interesting findings can be mentioned. Mentioned opportunities of the use of ICT highlighted among the health care personnel interviewed were: providing freedom, less dependency and increased security. They also pinpointed that the fear of a development towards a dehumanized care of the elderly is central when introducing ICT in health care services. Interviewed health care personnel believed that the fears of introducing ICT could be handled if the health care personnel and the management of the care organisations were conscious of their own basis of grounded values and risks involved. Regarding the relatives of the elderly using the videophone communication system, studied in this dissertation, four sub-dimensions are identified: to see is to maintain communication and freedom, to see makes me part of caring, to see is to be able to interpret the current well-being and to see is to confirm our relationship. These dimensions tell us a little about the relationship between the elderly and her/his relatives, and furthermore the users' relationship with the use of ICT. The author also suggests that an ICT solution can function as a tool for freedom but also as a tool for captivity. The freedom to choose to live at home longer can turn into a sense of captivity if the elderly who wishes to be placed at a nursing home are not allowed to do so due to technical solutions.

23- Being private and public at home – An architectural perspective on video mediated communication in smart homes [52]: This thesis deals with the question of how spaces for video mediated communication (VMC) can be designed and integrated into smart homes. The thesis contains two main perceptions of space: the conception of private and public spaces, and the idea of physical and digital spaces. Conclusions show that a novel modality of space, the public digital space, appears when VMC is introduced into smart homes. This modality is a relevant issue for the architectural profession and architectural research. The question of private and public is also relevant in the development of the CONFIDENCE system. Smart home solutions, similar to the CONFIDENCE system, are to be implemented in both new buildings and the existing stock of old buildings. This raises specific questions about the spatial layout and the typology of the housing (doorways, furniture, the construction of the home, house or flat etc). As the author states, the home is not a simple place to describe. The activities and processes are not always decided on by reason, efficiency or effectiveness. Habits and traditions as well as ethical and moral values have to be taken into account and emotions and satisfaction of desires can be of more importance than the usefulness of technical equipment.

24- Contemporary issues in ethics and information technology [53]: This book aims to be a useful source for dealing with practical ethical problems of IT – problems faced by professionals and users. The focus is a broad understanding of information technologies scoping from ethics of file transfers to the justice of the practice of moving jobs to low wage countries. The philosopher John Rawls' theories, particularly about justice based on the idea that justice means fairness to all concerned, are central in the search for answering the main questions in this book:

- What makes an issue an ethical issue?
- What features of information technology create new ethical issues?
- Who is to say what is right and wrong?

The author also mentions Justine Brandeis' take on individual principles as a strong Right to Privacy: people have the right to keep to themselves all matters not in the legitimate interest of the public. This principle is especially important dealing with monitoring solutions, centralized medical records etc. One of the conclusions suggest that ethical solutions must be based on higher level principles, because this is the only way we can deal ethically and consistently with the rapidly changing environment presented to us by IT.

25- Older adult's use of information and communications technology in everyday life [54]: This paper examines the extent and the nature of ICT access and use by older adults in their everyday lives. Information was collected from a sub-sample of 352 adults aged 60 years or more taken from a large household survey of ICT use in England and Wales. The findings suggest that using a computer is not only a minority activity amongst older adults but also highly stratified by gender, age, marital status and educational background. Nonusers are furthermore not a homogenous group of disempowered, under-resourced and under-skilled individuals and it does not seem that older adults fail to make use of computers because they lack formal access. The clearest reason found in the study for the non-use of computers is the irrelevance of ICT to older adult's lives. The authors suggest a "reshaping" of the ICT to fit better with the needs and lives of the elderly. This paper does not clearly discuss the ethical issues concerning elderly and ICT but can contribute with knowledge regarding how and why older adults use ICT solutions, with focus on computers and Internet.

26- Modelling ICT Perceptions and Views of Urban Front-liners [55]: The paper shows how a qualitative study can be used in order to understand the policy behind ICT investments in European Urban cities. The study illustrates that cities with socio-economic problems tend to see the municipality as a strong influence on ICT development, while cities with spatial problems do not view themselves as a dominant actor for the introduction of new ICT solutions. This paper does not include any ethical discussion and can perhaps be useful in constructing the business plan.

27- Safety and risk issues in using telecare [56]: This paper discusses questions about safety and risks in security systems integrated in elderly people's homes. A safety system prototype, MIDAS, is used as a case study. Ethical issues are not directly addressed but the safety and risks of a system such as CONFIDENCE are closely related to ethical issues towards the users and stake holders. The risks identified in this paper can be divided into three categories: environmental factors, human factors and technological factors. There are also different safety issues to be attentive of concerning the client, the carers (both formal and informal), the premises, the immediate community and the equipment. Conclusions state that these risks can be controlled through an integrated system approach, where the solution includes different safety systems that are integrated with each other. A self-controlling sub-system is also vital to limit the risks involved.

28- Mobile alarm system and mobility freedom. Original Swedish title: Mobilt larm och rörelsefrihet – Upplevelser av ett mobilt trygghetssystem [57]: In this research report the authors evaluate the Swedish project Mobile alarm system (Mobilt larm – MTL CDH) regarding how the system affects the freedom to move, integrity and safety. The main questions also include older person's views on functions and design of the system. The project evaluated aimed to study the use of safety alarm buttons and to develop a mobile safety alarm system. The project was also set to evaluate the experiences of the users from an empowerment point of view. Elderly people tested a prototype of the product and were later interviewed for the evaluation. This report concludes that the elderly (9 persons, 60-87 years old) think that the safety alarm button is able to give the user the freedom to move and security especially when portable/mobile. The interviewed also mentioned that the freedom to move and the feeling of security are closely linked, the sense of freedom increases with the sense of security. Another conclusion is that the elderly are afraid of something happening without anybody noticing it in time. This also includes the fright of being attacked outside. The interviewees are positive towards a system that could make them feel secure in these situations. The report also concludes that the test persons were positive towards the position determination system and did not see any problems regarding the integrity. The concern of not being found is a major factor in this conclusion. The people interviewed in this report were very positive towards the fact that they, as potential end-users, were able to contribute with their point of view on a technical product during the phase of development.

8 INFORMATION SHEET AND INFORMED CONSENT FORM TEMPLATE

These have been developed for the purpose of the “Scenario definition and analysis of end user needs and requirements” phase of the project. For purposes such as data gathering for algorithm development and testing, the content of these templates should be changed according to the research procedure which will be followed. Mainly section 1 in the information sheet should be modified: Explanation of the purpose and procedures. Approval of the local ethical committees should be obtained to comply with the adherence of CONFIDENCE to ethical principles in research, and the requirements of the EC FP7 programme.

For the research activities involving the collection of data on research subjects through functional ability tests, the possibility of incidental findings should be considered. Therefore the management plan to deal with incidental findings must be included in the information sheet and informed consent forms for these activities.



Information Sheet

(Insert the name of the organisation)

Date (Insert Date)

Title of the project: CONFIDENCE

Investigator: (Insert Name of the Investigator)

(Insert Organisation, Department's Name)

(Insert Telephone Number)

Participation in this study is voluntary and involves research subjects. Before agreeing to participate in this research study, it is important that you read the following explanation of this study. This statement describes the purpose, procedures, benefits, risks, discomforts, and precautions of the program. It also describes the alternative procedures available to you, as well as your right to withdraw from the study at any time. No guarantees or assurances can be made as to the results of the study.

1. Explanation of the purpose and procedures

You are invited to participate in a study that concerns the definition of the functions and features of a system that could help older people to gain confidence and security in their autonomous and independent living. This could help to improve their quality of life and an active participation in social life. The system's name is CONFIDENCE. CONFIDENCE will assist older people in their independent living both inside the home environment and outside the home. CONFIDENCE will be able to detect abnormal events, such as falls, losses of consciousness or unexpected behaviours that could be related to a health problem of the person. CONFIDENCE will be able to interpret situations and raise an alarm or issue a warning when necessary.

Participation in this study is voluntary and will take approximately (*number*) hours in different occasions. Participation in this study involves (*the research procedure should be detailed here*). The study sessions will be conducted in a setting that is mutually agreeable to the participant and the researcher.

2. Description of foreseeable risks and discomforts

There are not risks or discomforts that are anticipated from your participation in the study. Potential risks or discomforts might include possible emotional feelings when interacting with others or asked questions during interviews.

3. Benefits expected from the research to the subject or others

There is no direct benefit for participation. The anticipated benefit of participation is the possibility to affect the functions, features, and ease of use of the CONFIDENCE system which might help you and/or others to improve your/ their quality of life as autonomous and independent humans.

4. Alternative treatments

As this study does not involve specific treatments, there are no alternative treatments to participating in this study.

5. Cost and/or payment for participation in research

There will be no cost for participation in the research. The research subjects will not be paid to participate in this research.

6. Confidentiality of records

All information you provide is considered completely confidential, your name will not be included, or in any other way associated, with the data collected in the study. Not without your consent, the data collected during this study might be used for the purpose of other studies of the researchers in the project. The data will not be disclosed to a third party without your prior consent. The data which can identify you will remain confidential in a locked draw to which only the researchers of this study have access. The results of the studies will be published in research reports, professional conferences, and/or scientific journals. The information presented in these publications will always be anonymous. As a benefit to the society, this information will help others to provide quality services to older people. In accordance to the European and national laws, you can always exercise your data protection rights to data access, modification, or cancellation by contacting the investigator of this study.

7. Withdrawal from participation without penalty

Participation in this study is voluntary. Refusal to participate will involve no penalty to you. Each participant is free to withdraw consent, discontinue participation in this project, or have your data destroyed at any time without prejudice from this organisation.

8. Incidental findings

This research is not designed to examine your physical condition or functional ability. This is not a medical examination nor does it substitute the examination of a physician/medical professional that you could order for yourself if you have a health problem. However, if the researchers believe that there may be a problem that could deserve medical attention you have the right to be informed about it or not to be informed at all. It is possible that you could be unnecessarily worried if a problem were suspected but not actually found in a medical examination. In the informed consent form you will be asked what you would like us to do if we believe that a problem may exist. The options are:

* YES, I would like to be informed about the existence of a potential health problem, or

* NO, I would not like to be informed about the existence of a potential health

problem.

If you answer YES, after the researcher informs you about this potential problem, it is your responsibility to seek medical consultation about it. We may be able to provide you with more detailed information about this problem if you wish.

If you do not answer YES or NO to this previous question, as researchers, and solely in your own interest, we may consult for medical advice preserving your anonymity, and eventually may inform YOU about this potential problem.

9. Questions

Do you have any questions concerning the information you have just received?

For other questions concerning the research project and/or in the case of injury due to the project, research subjects can call (*insert the designated person in your organisation*) at (Insert the telephone number). For questions concerning your rights as a person in this research you should call (*insert the name and telephone number of the chairman of the ethics committee at your organisation, if applicable*)

We would like to assure you that this study has been reviewed and received ethics clearance through the Ethics Committee at (*insert the name of your organisation*). However the final decision about participation is yours.

Thank you for your assistance in this research.



Informed Consent

(Insert the name of the organisation)

Date (Insert Date)

Title of the project: CONFIDENCE

Investigator: (Insert Name of the Investigator)

(Insert Organisation, Department's Name)

(Insert Telephone Number)

Payment for research related injuries

(Insert Name of the Organisation) has made no provision for monetary compensation in the event of injury resulting from the research. In the event of such injury, assistance will be provided to access health care services. The cost of health services is the responsibility of the research subject.

Questions

Any questions concerning the research project and/or in the case of injury due to the project, research subjects can call (*insert the designated person at your organisation*) at (*insert the telephone number*). For questions concerning your rights as a person in this research you should call (*insert the name and telephone number of the chairperson of the ethics committee at your organisation, if applicable*)

Incidental findings

If during this research the researchers believe that there may be a problem that could deserve medical attention you have the right to be informed about it or not to be informed at all. It is possible that you could be unnecessarily worried if a problem were suspected, but not actually found in a medical examination. What you would like us to do if we believe that a problem may exist. PLEASE mark the box which applies to your choice:

YES, I would like to be informed about the existence of a potential health problem, or

NO, I would not like to be informed about the existence of a potential health problem.

If you answered YES, after the researcher informs you about this potential problem, it is your responsibility to seek medical consultation about it. We may be able to provide you with more detailed information about this problem if you wish.

If you did not answer YES or NO to this previous question, as researchers, and solely in your own interest, we may consult for medical advice preserving your anonymity, and eventually may inform YOU about this potential problem.

Agreement

I agree to participate in a study being conducted by Dr. (Insert Researcher Name) of the (Insert Department Name, if applicable), (Insert Organisation Name). I have made this decision based on the information I have read in the Information Sheet and have had the opportunity to receive any additional details I wanted about the study. I understand that I may withdraw this consent at any time by telling the researcher without penalty.

After the end of the project (mark the box for the option which suits you),

I would like to have my personal data destroyed,

I would allow the researchers of this project to use my data in other studies.

I also understand that this project has been reviewed by, and received ethics clearance through, the Ethics Committee at (the University of Jyväskylä or relevant organisation).

Name: _____ Researcher: _____

Signature: _____ Signature: _____

Date: _____ Date: _____

ACRONYMS

ACM	Association for Computing Machinery
APA	American Psychological Association
CONFIDENCE	Ubiquitous Care System to Support Independent Living
EC	European Commission
EGE	European Group on Ethics
EU	European Union
FIPP	Fair Information Practices Principles
HCI	Human Computer Interaction
IRB	Institutional Review Board
ICT	Information and Communications Technology
MRI	Magnetic Resonance Imaging
OAP	Old Age Pensioner
PAR	Participatory action research
RFID	Radio Frequency Identification
VMC	Video Mediated Communication
WMA	World Medical Association

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APPENDIX

Ethics Review 7FP Consensus Report Form

PROPOSAL PROGRAMME	PROPOSAL ID & ACRONYM	DATE OF CONSENSUS
FP7-ICT-2007-1	214986 CONFIDENCE	31-08-07

Ethical Issues Raised by this Proposal.

Adults Informed Consent Privacy Data Protection

Additional Comments – e.g. did the consortium fail to recognise specific ethical issues or have you identified other ethical issues not listed above.

None

Agreed consensus commentary

The proposal addresses a major issue for the elderly, which is assuming greater importance in view of changing European demographics. In general terms, the consortium is aware of the critical ethical issues

The consortium plans to develop a remote control positioning and microchange alarm system for elderly persons, who are liable to falls and other accidents. As such, the system is not preventive, but enables better user confidence and security. It is designed to be non-intrusive, protecting user-privacy, whilst permitting the elderly to preserve personal autonomy and activity in society.

CONFIDENCE is committed to observing the Charter of Fundamental Rights of the European Union, as well as other ethical requirements. Within the proposal, WP6 deals with monitoring of ethical (and other) issues; the project leader will also act as data controller. It would be appropriate if the consortium specified which ethical issues could be expected at that point, especially in task 6.2. Close collaboration will be required to address the end-user issues of consent, privacy and data protection

The relevant EU Directives, and articles (96/46 and 58/2002), are identified

The proposal describes how research subjects will be involved in the research, providing them with information about the research activities, duration of their participation, and which procedures are to be followed. The informed consent process appears appropriate and clearly states that there is no direct benefit from participation and subjects can withdraw at any stage, without penalty.

Data protection and confidentiality issues are addressed, with a good description of respect for elderly privacy and the proposal of an ethics code to be signed by consortium members.

However, the information states that “data collected during this study will be retained indefinitely and may be used for the purpose of other studies of the researchers in the project”. In order to respect the autonomy of the study participants, it would be more appropriate to provide subjects with the option of having their data destroyed following the end of the project.

The usability tests are well described. Regarding the validation phase, the national legislation in each participating country will be respected (specific details are not given and it could be helpful for investigators, at an early stage to have their obligation clearly laid out e.g. in the aforementioned ethics manual).

The specific issues raised by the proposed study have been comprehensively discussed with the applicants demonstrating a significant understanding of the ethical issues and the relevant legislation/guidelines required in relation to a study of this kind. The consortium have made a genuine commitment to a user-centred approach with respect to the proposed research and have included consultations with older people and their carers at several intervals during the research process. The user will have control over the system and can customise alarm protocols.

Overall Impression: Excellent Good Inadequate

Requirements: (Requirements become contractual obligations).

Copies of local research ethics committee approvals and informed consent documents must be submitted to the EC prior to commencement of relevant research activity. Details on relevant legislation/guidelines applicable to the study at either national or international level must be submitted to the Commission and circulated to consortium members prior to the commencement of the study

Recommendations: (Advice to applicants but not compulsory).

1. The consortium should give some consideration to drafting an ethics manual and disseminating the manual amongst the consortium partners in advance of the first annual report
2. Privacy issues might be underestimated; the scenarios of potential misuse (i.e. input for insurance companies, a.s.o.) should be elaborated. This could be a very valuable starting point for the code of good practice.
3. Subjects should be given a choice on the informed consent form in relation to the indefinite storage of their data and secondary uses of that data by members of the consortium. This would require re-drafting the information leaflet.
4. A disclosure plan should be drawn up to deal with incidental findings.