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D2.3 European country policies and ethical package

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Executive summary

What is ethics and why is ethics important? Ethics may leave many people confused, unsure of what they are dealing with. And it is a complex field; ethics is a not a fixed or static field, but one that is deeply embedded in its historical, social, cultural and legal context. Ethics is the philosophical study of right and wrong but outside academia; ethics can be defined as the moral standards that help guide behaviour, actions, and choices. Which is why ethics is so important; it is closely related to concepts of fundamental human rights, e.g. the right to life or the right to human dignity as stated in the Charter of Fundamental Rights of the European Union [1].

The ethics of information and communication technology (ICT), also named as computer ethics, is a relatively new subject area. It deals with the social impact of computer technology and its uses. With the digitalisation of European society, the focus on the ethical aspects of ICT can be seen in various EC communications and directives. Particularly, in relation to senior citizens and frail people the ethics of ICT is important; the digitalisation of our society is in effect excluding most senior citizens as the digital divide is mainly age-related. This in itself represents an ethical issue. Nevertheless, ICT represent a great asset to assist senior citizens in living healthier and longer at home, and as long as the ethical aspects are carefully considered and taken into account, and technology isn't mistaken for an objective value-free entity, users and society can greatly benefit. Which is the aim of inCASA; namely to provide a truly beneficial and ethically sound solution which includes a careful assessment of the ethical issues involved such as privacy and data protection, surveillance, autonomy, dignity, and informed consent.

Privacy and data protection are ensured by law but it is nevertheless useful to examine the ethical implications of this issue. These include: what information is collected by the system, controlled (not excessive) use, for what purpose the information is used, to whom it may be transferred, user's access to information and the possibility to correct personal information, storage, etc. Healthcare and assistive technology may cause an erosion of privacy and it is therefore crucial that proper measurements (including those embedded within the technology per se) are taken to protect the individual's data and privacy.

Closely related to privacy and data protection is the issue of surveillance. The remote monitoring of e.g. habits (as proposed by inCASA) has the clear benefit of being able to raise alarm if e.g. a normally active user is found lying in bed or worse, on the floor, all day. The ethical problem is how one can ensure that monitoring and surveillance technologies do not violate the individual's right to privacy or in any way endangers the protection of personal data. Also, a person's autonomy may be threatened in this context; these technologies may create dependencies or diminish the person's agency, for example taking away the possibility of "opting out". This in turn threatens the person's right to dignity. According to the European Charter of Fundamental Rights, dignity includes i) the right to life and ii) the right to the integrity of the person, which also implies the right to the free and informed consent of the person concerned. These two aspects are very relevant in the context of healthcare and assistive ICT.

Informed consent is a vital tool for dealing with ethical implication of a certain technology. A perquisite for informed consent is obviously that the user (or participant) fully understanding the technology and its use. inCASA will ensure that informed consent is obtained from all end-users (i.e. patients and residents who will use the proposed solution in the pilots).

inCASA's Ethical Guideline is defined in this document. The Ethical Guideline takes the form of a series of questions, a check list, which will make the assessment of whether the Ethical Guideline is followed more simple and straightforward. The Ethical Guideline is a tool for all partner to use, however, the inCASA Ethical Board is responsible for overseeing that the Ethical Guideline is adhered to. The inCASA Ethical Board Terms of Reference are also defined in this deliverable.

1 Introduction

The inCASA project is committed to ensuring that the fundamental ethical principles are respected and that any ethical concern or issue is properly dealt with if and when it should occur. This includes taking into account the ethical issues related to the technological solution *per se* that inCASA is proposing as well as the actual running of the inCASA pilots that involve end-users testing the solution.

As demonstrated in D2.1 Preliminary user requirements investigation, age and ageing are cultural constructs meaning that they need to be understood in their cultural and social context. When situating age and ageing in relation to information and communication technologies and the continued digitalisation of European society, it also becomes clear that information and communication technologies (ICT) are not value free or objective, but actually influence dominant perceptions of e.g. age and ageing. Think of the digital divide. The digital divide in Europe is largely age dependent; senior citizens are far behind their younger co-citizens when it comes to ICT skills and this fact puts senior citizens at a disadvantage (they become excluded) as society becomes more and more digitalised and ICT are becoming more widespread in areas such as healthcare. Perceptions of age and ageing thus take on a particular meaning in relation to ICT and vice versa. The digital divide and social exclusion/inclusion (e-inclusion) of senior citizens is an ethical problem because it offends the principle of justice. Put in another way "e-Inclusion is necessary for social justice, ensuring equity in the knowledge society." [2]

Seeing that inCASA is using innovative ICT to assist and support frail people and senior citizens (used here to describe people over the age of 65[1]) as assessment of the basic ethical issues related to senior citizens and ICT is necessary. But the ethical implications do not stop here. The nature of the proposed inCASA solution also affects the ethical aspect of privacy and protection of data (inCASA services will generate sensitive data, including health data), surveillance, dignity and autonomy. Being aware of and understanding these ethical matters is a prerequisite for ensuring that the project is ethically sound and participants' fundamental rights are not violated.

Most importantly, as real end-users (as in senior citizens, patients, residents) will be testing the inCASA solution through their participation in the pilots, informed consent is absolutely necessary and will be obtained prior to the pilots' start. Also, pilots will obtain any necessary approval by their local ethical committees.

1.1 Purpose and content of this deliverable

The purpose of the present deliverable is to "define an ethical guideline against which the pilots must comply"[2]. In order to do so, the ethical issues that are relevant for the inCASA project are first analysed. Subsequently the ethical guideline is defined in terms of a check list (Ethical Guideline Check List) with questions related to each of the five main ethical issues relevant to inCASA: privacy and data protection, surveillance, autonomy, dignity and informed consent.

The check list format has been adopted because it provides a clear and straightforward tool for defining the ethical guidelines and, importantly, a useful tool for assessing easily whether these guidelines are actually adhered to. The check list format makes it quite simple to identify any potential or actual ethical problem that requires action. The majority of questions require a simple yes/no answer. For example, in relation to informed consent, the check list asks: "Has the project obtained the free and informed consent of those persons involved in or affected by the project?" The answer "yes" demonstrates compliance to the guideline, whereas "no" demonstrates non-compliance, and thus that this must be remedied.

[1] We do not intend to suggest that people over the age of 65 constitute a homogenous group in any way (age is but only one common designator) but are using this label purely to make clear that we are focusing on this particular age group.
[2] inCASA Description of Work, Annex 1, p. 10.

1.2 Outline of this deliverable

The purpose of Chapter Two is to take a closer look at what is ethics, particularly ethics in the context of ICT and senior citizens as this is the context of inCASA. The chapter will give the reader an understanding of the main ethical issues at stake here.

Chapter Three analyses the five main ethical issues at stake in the project, i.e. privacy and data protection, surveillance, autonomy, dignity and informed consent. The Ethical Guideline Check List is presented here, which consists of questions is defined for each of these issues which will help to assess that the pilots are run in compliance with the Ethical Guideline.

Chapter Four provides an overview of various EU policy documents and ethical guidelines in relation to the practice of medicine which are relevant to inCASA.

Chapter Five outlines the specific national regulations for the countries where the inCASA pilots will be carried out. Information of whether ethical approval is necessary will be provided as well as where and how to obtain this.

Chapter Six briefly explains the purpose of informed consent and the process of obtaining this from the pilot end-user. The inCASA standard informed consent form and other relevant documentation can be found in the appendices.

Chapter Seven constitutes the inCASA project's Ethical Policy.

Chapter Eight presents the Terms of Reference for the inCASA Ethical Board.

2 What is Ethics?

Ethics is the philosophical study of right and wrong. However, one need not be a philosopher to discuss ethics or to have an understanding of what ethics is or whether something is ethically correct (or safe) or not. Generally, in all areas of life we all have some idea of what may be deemed ethical or unethical. These ideas are socially and culturally determined and as such subject to interpretation, but we may nevertheless talk about dominant (i.e. socially accepted and agreed upon) customs, values, practices and rules which indirectly and/or directly determines our social actions and behaviours, and what we deem as acceptable and ethical. For example, the Charter of Fundamental Rights of the European Union [1] defines certain shared values and as such serves as formal ethical guidelines.

In other words, ethics are close to morals; whereas the concept of ethics may leave most people with the impression of something very philosophical, theoretical and to an extent intangible, the concept of morals may be easier to grasp as morals take on a more practical and tangible meaning for most people. Ethics and morals are thus closely interconnected and we may thus define ethics as the moral standards that help guide behaviour, actions, and choices.

We find ethics and ethical rules of conduct or principles in various contexts; each is specific for its context (including national context). For example, in a business context, we often find that companies have a code of conduct, which in essence defines the company's ethics or moral standards in relation to internal and external practices. In a medical context, there are also specific ethical principles and rules; perhaps the most important one being the International Code of Medical Ethics which e.g. states that "A physician shall act in the patient's best interest when providing medical care." [3] The World Medical Association (WMA) has also set out various ethical principles in the Declaration of Helsinki [4] and the Declaration of Geneva [5].

However, overall these different, and specific, ethical standards or rules of conduct should not violate legally recognised (human) rights such as those set out in the Charter of Fundamental Rights of the European Union.

2.1 The Ethics of ICT

The field of ethics in relation to ICT is more commonly known as computer ethics. Computer ethics may be defined as "the analysis of the nature and social impact of computer technology and the corresponding formulation and justification of policies for the ethical use of such technology." (Moor, 1985) [6]

The creation of the field of computer ethics is generally credited to Norbert Wiener dating back to the 1940s. However, it was not until 1985 that the field really took off with the creation of various journals, textbooks, university courses and degree programmes, conferences and websites etc. As computer technology has continued to develop, so too there exists now a number of subfields of computer ethics, such as cyborg ethics, "agent" (robots) ethics, global information ethics, information technology and genetics, computing and terrorism etc. [7]

What are the social and ethical impacts of ICT on our society? There is no straightforward answer to this question as it is very much context dependent, i.e. what kind of ICT are we talking about, how is it used, by whom and why etc. In this sense, we are dealing with applied ethics as we wish to define the impact the possibilities of ICT have on our lives, health, security and opportunities ect.

In the European context, some important documents related to ethics and ICT are the Riga Declaration [8], Aging well in the Information Society [9] and i2010 [10].

These documents call for an increased ethical awareness in relation to ICT, particularly in the context of e-inclusion, assistive technologies in healthcare, and the aging population. For example, the Bled Report states "ICT ethics demand that we look beyond legal compliance to moral requirements when planning, developing and implementing ICT systems." [11]

The Seventh Framework Programme (FP7), Article 6 Ethical Principles (§1) states: "All the research activities carried out under the Seventh Framework Programme shall be in compliance with fundamental ethical principles". [12] Not only compliance with ethical principles but also an acute awareness of the ethical aspects of a project or in relation to the development of new ICT is a prerequisite and good practice.

Also, compliance with legal requirements and codes of conduct is obviously a must. Failure to do so will hinder the deployment of new ICT services or appliances on the market. As pointed out above, legal guidelines and directives have a certain ethical element to them but they cannot be substituted with properly defined ethical guidelines. Nor do they specify the particular ethical issues at stake for specific ICT or how to resolve these. In fact, it would be impossible to define a full list of all the ethical issues embedded in ICT or how to resolve these because as technology continues to develop and new systems, services, devices and appliances are realised, so will new and/or different ethical issues arise.

Being aware of the potential ethical dilemmas is the very first step in addressing and solving these, ideally before they become a reality, i.e. before a system or application is put on the market or implemented. This is particularly important as it can prevent the market failure of a system or application due to unforeseen ethical problems that cause end-users or producers to reject it. Also, having to readjust or redesign a technology in order to meet ethical requirements is often very complicated and expensive and may simply not be feasible thus also causing the product to be rejected [13]. Another advantage is that awareness of ethics offers us a way to focus on the needs of the end-user. Ethics ought to be considered at the onset in order to prevent future misuse or violation of fundamental rights and ethical principles, and here we see that this point also has a very practical marketing aspect as well.

It is worth noting that it may not always be the case of the technology *per se*, but how it is used that causes ethical problems [14]. Overall, it should be safe to say that ICT are developed with the aim to provide some sort of benefit to society and individuals, whether it shall be more effective work procedures, assisting the ageing or people with chronic diseases, optimising existing services etc. It is crucial to look beyond the instant obvious benefit a technology is meant to offer and look at it in the context of "the big picture". Only by doing so, is it possible to analyse and define the ethical issues embedded in the technology and its use.

For example, a surveillance system which can monitor and track e.g. a person who is dement in order to avoid the person from wandering and potentially getting lost or come to other harm, or to monitor the habits of an elderly person with health problems so as to be able to detect any deviation which may suggest a fall and thus need for alarm and help, has clear benefits. However, at the same time it raises the ethical issue of the right to privacy. If the technology is used without the informed consent of the person who is being monitored, the real ethical problem is not the technology *per se*, but how it is being used.

It is therefore important to carefully consider and analyse the ethical issues concerning any particular technology and how it is being used, and then take the appropriate measures to overcome the particular problem and thereby ensure that the fundamental ethical principles are not violated.

2.2 Senior Citizens, Ethics and ICT

Europe is ageing and it is predicted that by 2020, 25 per cent of the EU's population will be over 60.[3] This demographic development will have serious social and economic impacts on Member States, in particular, on healthcare and the workforce. Overall, ICT are considered as key to the ageing challenge; assistive technologies may help seniors and people with health problems to remain independent and at home, thus providing a tool for enhancing their quality of life as well as for controlling spiralling healthcare costs and making up for the shortage of healthcare personnel.

[3] Commission Staff Working Document, Accompanying document to the Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions, Ageing well in the Information Society, SEC (2007) 811, Brussels, 14 June 2007, p.6.

As inCASA is mainly aimed at people aged 65 or more (whom we here refer to as senior citizens), it is here appropriate to take a special look at ICT in relation to senior citizens. The deliverable D2.1 Preliminary user requirements investigation gave an overview of age and ageing and described how senior citizens have special user needs and requirements in relation to ICT, particularly healthcare and assistive ICT (ICT for ageing). These special needs – if not considered and accommodated for – may in effect exclude many senior citizens; notably, the digital divide is mainly age related. The digital divide basically refers to the gap between those people with effective access to digital and information technology and those without such access.

As explained in D2.1 age and ageing is *not* just about looking at chronological age; understanding the meaning of age and ageing requires an awareness (and analysis) of the social and cultural context in which people age. With the development of ICT and the increased digitalisation of society, new social structures, norms and values have emerged. Moreover, issues of engagement, inclusion and exclusion (particularly e-inclusion and e-exclusion) of senior citizens have become very relevant with the development of ICT and the digitalisation of European society. ICT for ageing may reinforce both positive and negative ideas of what it means to be old.

In the context of e-inclusion, digital competence of senior citizens refers to the capacity to use ICT as a tool for self-awareness and communication. Research has shown that senior citizens are generally not technophobic but they are often quite critical and selective in their use of computers and the Internet. More importantly, senior citizens often need more time and special teaching methods to learn how to use ICT and perform simple computer tasks. Often senior citizens feel that they are “too old to learn”; which likely a perception moulded by dominant social perception about ageing, than by seniors themselves [15].

Complex technologies and poorly designed user interfaces may not only exclude senior citizens, they may also reinforce a feeling of low self-worth, insecurity, dependency and low social status. On the other hand, truly assistive, supportive and user friendly technologies may increase inclusion as well as positive feelings of self-worth, ability, confidence, independence and social status.

Inclusion, or e-inclusion, is (as noted above) an important issue in relation to senior citizens, ICT and the digitalisation of society. Inclusion/exclusion has been on the agenda in the EU for some time now, including policies and directives that promote inclusion of elderly people and people with disabilities, and DG Information Society and Media adopted the notion of e-inclusion which “refers to the actions to realise an inclusive information society, that is, an information society for all”. The main goal of e-inclusion is improving ICT access for disadvantaged groups and populations, particularly for people with disabilities and senior citizens, and to contain frailty and promoting independent living by using assistive technologies, which have important ethical implications. In fact, ethics are an integral part of the EU concept of e-Inclusion: “e-Inclusion is necessary for social justice, ensuring equity in the knowledge society.” [2]

In the communication on Ageing well in the Information Society [9] the ethical aspect of e-inclusion is demonstrated clearly: “Solutions can only bring benefits if users have access to basic ICT facilities, have the appropriate education and motivation, and ethical and psychological issues are properly addressed. There is no specific reference point for ethics in ICT for ageing, for example, in safeguarding human dignity and autonomy where solutions require a degree of monitoring and intervention.”

As this quote suggest, it is crucial to consider the ethical implications of ICT for ageing, such as healthcare and assistive technologies, and to ensure that they are ethically sound and do not violate fundamental human rights. In addition to dignity and autonomy, the issues of privacy and data protection, surveillance, and informed consent are equally important and these issues will therefore be analysed in the following paragraphs. First, however, a closer look at what we are dealing with when talking about ageing well in the information society.

2.2.1 Ageing Well in the Information Society

The action plan on Ageing well in the Information Society [9] highlights three areas of user needs that need to be addressed:

- Ageing well at work or 'active ageing at work': staying active and productive for longer, with better quality of work and work-life balance with the help of easy-to-access ICT, innovative practices for adaptable, flexible workplaces, ICT skills and competencies and ICT enhanced learning (resp. e-skills and e-learning).
- Ageing well in the community: staying socially active and creative, through ICT solutions for social networking, as well as access to public and commercial services, thus improving quality of life and reducing social isolation (one of the main problems of older people in rural, scarcely populated areas, as well as urban areas with limited family support).
- Ageing well at home: enjoying a healthier and higher quality of daily life for longer, assisted by technology, while maintaining a high degree of independence, autonomy and dignity.

Ageing well at home and ageing well in the community are particular relevant to the inCASA solution.

2.2.1.1 Ageing well at home

Information and communication technologies in the home have the potential to allow senior citizens to live independently and stay at home for longer rather than move into a nursing home. In the home domain, we generally refer to these technologies (i.e. home based systems or devices) as assistive technologies and these may be designed in a way that they become ubiquitous. The term "ubiquitous communication" is used to describe the ability of objects and devices embedded in the everyday environment to communicate seamlessly with each other and with other structures, such as humans, external data repositories and other electronic resources, thus supporting a wide range of applications and services.

Adding (seamless) communication abilities to ubiquitous computing devices opens up for a whole new world of services based on "context awareness". Services can obtain information about the circumstances under which they are able to operate and based on rules, or an intelligent stimulus, they can adapt their behaviour accordingly[4]. Services can ubiquitously sense the user's context while simultaneously accessing remote data repositories and other humans, and exchange information without the user being involved or even aware!

There is no doubt that assistive technologies may in fact be very useful and assistive, particularly when they function as a compensatory system or device to e.g. impaired hearing, sight or other physiological attribute. However, we need to ask ourselves for *whom* the technology is assistive? The carer, the senior citizen/patient, or a combination of both? The answer may depend on the type and use of a specific technology. Nevertheless, this is important to consider because it affects how we define the ethical, social and legal implications. One can imagine that if a specific assistive technology is defined as first and foremost a technology assisting the carer, the ethical focus will thus centre on the carer. As important as such ethical considerations may be, it is also crucial to consider how the recipient of the carer's care is affected; how the care per se is affected.

This raises another important ethical issue, namely if and how an individual can opt out of being supported by assistive technologies. This is particularly acute if the technology in question is defined as assistive to the carer rather than to the senior citizen/patient. As such, we may distinguish the senior citizen as either (roughly speaking) a passive recipient or a proactive end-

4 Ubiquitous communication is thus the engine that drives many innovative, in particular mobile, services in areas such as healthcare, social services, building and home automation, security and many other areas.

user. As a (passive) recipient, opting out will be considerably more difficult and complex, thus jeopardising or decreasing the person's autonomy.

The differentiation between recipient and end-user is also likely to influence the person's attitude and behaviour in relation to assistive technologies, as well as to which contexts the technologies are accepted or not. Other factors are also relevant to consider, for example the individual's personal situation, acceptance of needing help, willingness to talk about it, self-perception etc. The issue of deciding when and how assistive technologies should be implemented to assist a person (i.e. the senior end-user) must take the individual situation and the relevant context under consideration and also be adapted to individual needs, including decisions of opting out.

Ageing at home raises other crucial ethical questions, most notable perhaps the trade-off between privacy and security. Assistive technologies at home, such as monitoring and surveillance technologies erode the traditional boundary between private and public space – even if the public access to private data, to the home sphere, is restricted. However, this erosion may be accepted if the perceived benefits in terms of increased security are deemed higher. As this will necessarily be a subjective perception, we may at best only be able to point to the different pros and cons, rather than point to a fixed solution to this trade-off dilemma.

2.2.1.2 Ageing well in the community

Social relations and social interaction are changing with the development of information and communication technologies and systems. These technologies are also changing notions of social interaction and relationship, as well as the notion of community. Online communities are a reality and they may provide great support for many people, e.g. online support groups for people with health problems or recreational/interest groups. In terms of ageing, perceptions of age and ageing are also changing with the development of e.g. assistive technologies which can support people to remain active, or become active in new ways in the community.

We may question whether ICT are thought to be assistive, thus providing support designed to individual needs and wishes, or whether they are thought to be enhancing, thus disguising any physical or mental impairment brought on by age. The distinction is perhaps best thought of as one between adapting the environment to the individual and adapting the individual to the environment. It is thus a case of different value models and perspectives, which proves to us yet again that technology is not value free or objective. It is the application and implementation of technologies that raises ethical questions; i.e. which value model and perspective predominates.

The physiological and psychological changes caused by ageing often prevent seniors to participate in the community to the extent they may wish. Visual and hearing impairment and decreased mobility are common among senior citizens. In general increased disabilities affect senior citizens and the ethical problems for the disabled and the elderly therefore overlap somewhat. Nevertheless, it is important to distinguish and also to emphasize that senior citizens do not constitute a homogenous group, but indeed a deeply varied group of people who interact in different social settings, and at different times in life. ICT have the potential to allow senior citizens to continue their engagement in specific social settings or communities by providing necessary support and assistance. At the same time, these technologies may actually create access to new communities, thus either changing or increasing the individual's social network and possibilities of engaging actively in social relations.

As in other realms, equal and just access to assistive technologies that provide support for ageing well in the community is an ethical prerequisite. At the same time, the choice of opting out must be available. Healthcare and assistive technologies, particularly when these are ubiquitous as it is often the case (if not the aim at least), on account of being ubiquitous, make this choice less obvious, or even less feasible, because the technologies will not be very visible or obvious to the user. This affects not just the person who is assisted directly but also his or her family, friends, carers and peers. For example, as they enter the person's home, in this case a smart home where

ubiquitous communication technologies are installed (e.g. sensors, monitoring and surveillance devices), how can they control that their movements, personal data etc. are also not extracted and processed automatically? Or the other way around, as the person engages in different communities outside the home, how will other participants in the community be affected? Issues of privacy and autonomy (i.e. as in having control of the technology or access to control devices) are particularly acute here. It is therefore necessary to highlight the various issues, the pros and cons, and to design the technology to be able to adapt to individual demands, in order to allow each individual to determine and establish the level of privacy and autonomy they require.

As we have shown here, there are various ethical issues related to ICT for senior citizens. In the following chapter the main ethical issues relevant to the inCASA project will be investigated further and inCASA's Ethical Guideline will be presented.

3 inCASA Ethical Guideline

This chapter presents inCASA's Ethical Guideline. In order for the ethical guideline to have a real practical value, it has been phrased as questions in a check list. This should make it straightforward and easy to assess if the Ethical Guideline is actually being followed. Most questions require simple yes/no answers while others require more in-depth answers to demonstrate that the proper measures and/or precautions are in place.

In other words, project partners, especially the pilots, can refer to this check list at any stage and continuously to simply check if they follow the Ethical Guideline. The Ethical Board will also use this guideline/check list as a tool for assessing whether the pilots adhere. If a violation is either foreseen or actually committed the Ethical Board will become involved and act as defined in the Ethical Board Terms of Reference (Chapter Six).

As a background to the ethical guideline, the main ethical issues relevant to inCASA are first analysed. These issues are: i) privacy and data protection, ii) surveillance, iii) autonomy, and iiii) dignity. These issues should be considered not just in relation to the actual running time of the pilots but also to what happens after the pilots or if an end-user decides to leave the pilot.

An overview of the Ethical Guideline Check List can be found in Appendix A.

3.1 Privacy and Data Protection

Constant observation or monitoring of the end-user and his/her daily context raise obvious data protection and privacy issues with regard to both the user him/herself, and his/her occasional or regular visitors (whose interactions with the users, movements within the users' home etc. will also, as a matter of fact, be observed and recorded). Automatic and constant monitoring and observation, including in the bedroom and other private rooms, dramatically decreases the user's intimacy. Living under constant observation and monitoring obviously decreases the user's expectations of privacy, with the consequences that the user may feel compelled to exercise some kind of self-censorship with regard to his spontaneous behaviours, interactions with others, and attitudes.

The main important privacy/data protection issues are: what information is collected by the system, controlled (not excessive) use, for what purpose the information is used, to whom it may be transferred, user's access to information and the possibility to correct personal information, storage, archiving and destruction of information obtained, user information, proportional use, communication of information to third parties, and security measures embedded in applications to avoid data leakages, alteration of information or 'cloning' of the captured information.

With respect to the data-protection, technical and policy provisions should be developed to protect the confidentiality of the processed data, while simultaneously enabling efficient access to the information for diagnostic and therapeutic purposes. Moreover, as far as medical data are involved, issues of medical confidentiality are obviously involved as well. How such a system would impact on the patient-doctor relationship and on the trust level presupposed in such a privileged relationship must be assessed.

In the legal context, the right to privacy is a human right and is protected by legislation. Article 8 of the European Convention for the Protection of Human Rights and Fundamental Freedoms states that:

> 1) Everyone has the right to respect for his private and family life, his home and his correspondence.
>
> 2) There shall be no interference by a public authority with the exercise of this right except such as is in accordance with the law and is necessary in a democratic society in the interests of national

> security, public safety or the economic well-being of the country, for the prevention of disorder or crime, for the protection of health or morals, or for the protection of the rights and freedoms of others." [16].

Also, Article 8, no 1, of the Charter of Fundamental Rights of the European says that: "Everyone has the right to the protection of personal data concerning him or her." [1]

Another related issue is the right to check the accuracy on one's personal data. In this regard, the OECD guidelines say that personal data should be accurate, complete and kept up-to date. [17] Also, Article 6 of the EU's Data Protection Directive states that personal data must be accurate and, where necessary, kept up to date. [18]

As we see here, privacy and the protection of data are closely linked. Furthermore, the right to privacy includes the right to control our personal information, i.e. to control who has access to our personal information and what kind of information others have access to. It is crucial to ensure that ICT will not violate human rights such as the right to privacy. The importance of this cannot be stressed enough in the light of the fact that our lives are becoming more and more online. Privacy and the protection hereof, have taken on a digital dimension, especially as ICT are increasingly used to collect, store, analyse and distribute personal data. This raises the ethical issue of how to secure that the individual maintains the power to control and protect his own personal data.

With respect to the data protection, technical and policy provisions should be developed to protect the confidentiality of the processed data, while simultaneously enabling efficient access to the information for e.g. diagnostic and therapeutic purposes. Some of the main data protection issues are what pieces of information are collected by the system, controlled (not excessive) use, for what purpose the information is used, to whom it may be transferred, user's access to information and the possibility to correct personal information, storage, archiving and destruction of information obtained, user information, proportional use, communication of information to third parties, and security measures embedded in ubiquitous applications to avoid data leakages, alteration of information or 'cloning' of the captured information.

3.1.1 Relevance to inCASA

In relation to the inCASA solution, it is particularly important to consider the following areas of privacy: privacy of the person (the body), privacy of personal behaviour, privacy of personal communications, and privacy of personal and medical data. These technologies can create an erosion of privacy; consider a healthcare scenario where the user (or his/her family) is forced to compromise between privacy and security, e.g. created by monitoring and surveillance healthcare systems. In fact, surveillance technologies (see below) pose a particular challenge to the issue of protection of privacy and personal data.

3.1.2 Check list

Asking the following questions will help to assess whether the inCASA pilots violate the project's ethical principles in relation to privacy and data protection:

- Is information collected in ways of which the data subject is aware?
- Will the information be deleted when it is no longer needed for the purpose for which it was collected?
- Who will have access to or use of the data collected?
- Will the data be transferred to or shared with others?
- Has the project taken steps to ensure that persons cannot be identified from the data to be collected?
- What assurances exist that the information collected is true and accurate?

- Has the project taken measures to ensure protection of personal data, e.g., by means of encryption and/or access control? If so, what are they?
- Have measures been put in place to facilitate the person's access to his or her personal data?
- Can the person whose data are collected rectify easily errors in personal data? What procedures are in place for doing so?

3.2 Surveillance

Surveillance technology affords the elderly or frail people the possibility to remain in their own homes despite certain medical conditions. Telemedicine permits them to "visit" the doctor without leaving the comfort of their own homes and robotics make it possible for them to receive assistance without having to depend upon care givers. However, while such advancements allow the elderly to maintain communication and to live as autonomously as possible for as long as possible, they also pose the risk of alienating and isolating them. This represents an ethical problem if one is not careful; the aim should be to use technologies to support and *not* replace.

Surveillance technologies also raise other ethical dilemmas. The problem is one of consoling the perceived benefits with intrusion of privacy. In the context of healthcare ICT, e.g. assistive technologies, we can take the example of remote monitoring and surveillance. The obvious benefits as already mentioned include improved control and management of chronic conditions, allowing people to stay at home for longer (including allowing "hospitalisation at home"), and making healthcare services more efficient. There are also explicit surveillance technologies that are designed to track the movement of an individual, e.g. sensors in exit doors in care homes that warn staff when someone is leaving. The rationale behind the use of this is obvious to prevent for example someone with dementia from unwanted wandering and as such is for the protection of the dementia patient. Also, using monitoring technology to monitor habits as proposed by inCASA has the clear benefit of being able to raise alarm if e.g. a normally active user is found lying in bed all day or in the bathroom for several hours etc.

However, it still raises serious ethical problems in relation to protection of this person's privacy. All these services rely on the transmittance of personal medical data and on a certain degree of surveillance of the individual. The ethical problem is how one can ensure that monitoring and surveillance technologies do not violate the individual's right to privacy or in any way endangers the protection of personal data.

A related issue is the issue of autonomy (see below). Surveillance technologies may threaten the person's autonomy in the sense that he/she begins to exercise self-censorship and/or simply loosing the feeling of autonomy as a consequence of being constantly observed and monitored.

3.2.1 Relevance to inCASA

The inCASA pilots will be monitoring their end-users at home with the aim of improving the management and control of the end-user's health status by monitoring specific health parameters (e.g. blood pressure, oxygen saturation levels, weight, and heart rhythm), monitoring behavioural patterns (e.g. movement and contact) and/or home environmental parameters (e.g. room temperature and gas/water leaks). This monitoring will in some cases be constant for a period of time and in other cases at specific times of the day or week.

Although all end-users will have given their informed consent to be monitored, they may end up feeling that their privacy is being invaded after a while; people may imagine how they will feel about being monitored but the real experience of being monitored may be different (negatively or positively). In particularly, the behavioural and home environment surveillance and monitoring may cause end-users to feel that their privacy has been invaded, and it is therefore important that the inCASA pilots are acutely aware of how end-users react and feel (and that these feelings may change several times over time) once the pilots are up and running.

The fact that these technologies will be installed in the end-users' home also makes it vital to consider how this may affect the other household members, guests and professionals (social workers, healthcare professionals, building maintenance workers etc.). This especially concerns the behavioural and home environment monitoring, e.g. indoor movement sensors (ATC pilot).

3.2.2 Check list

We may thus consider the following issues:

- Have any signs or other notifications been made to alert people to the presence of CCTV cameras or other surveillance devices?
- How and for how long will images or data be retained?
- How will such images or data be used or erased?
- Who will authorise the surveillance practice, whether in private homes or assisted living residences?
- What measures will be put in place to avoid abuses where, for example, surveillants watch others engaged in behaviour that generally accepted social norms would regard as intimate or private?

3.3 Autonomy

An essential ethical problem with the use of ICT in healthcare concerns the notion of autonomy. On one hand, healthcare and assistive ICT may reduce the dependency on consultation of physicians; enable a less restricted daily life, and/or increase patient's self-determination. On the other hand, the technology may threaten the patient's autonomy in the sense that it generates a new type of dependency, i.e. on the new technology, and creates a huge amount of personal data beyond the patient's control. However, dependency may vary with respect to the use of the technology in question. To enable self-determined use of the technology, patients should be educated.

Autonomy includes having control of the system, i.e. that the (informed) user is able to switch it on or off. One may here ask what is the point then if users can freely switch the system on or off? However, the issue is in reality not different from the traditional healthcare setting where the patient may choose whether or not to follow the doctor's orders. The ethical requirement here is that the patient is made fully aware of the consequences of non-compliance. This is also the case with assistive and healthcare technology, although here the patient also needs to be made fully aware of the consequences of the use of and compliance with these technologies, e.g. the impact on/invasion of privacy.

Assistive technologies should always remain 'assistive' in the sense that they should not take control over someone's life. Take the example of ubiquitous ICT in the context of ambient assisted living systems. The constant recording of the user's compliance with medical advice and/or medication, may threaten the user's autonomy and agency as compliance or non-compliance *per se* ceases to be an option.

In relation to ambient assisted living (AAL) systems, the issue of autonomy poses another serious ethical problem, which we may refer to as 'technological paternalism'. Although AAL systems are meant, and, to a large extent, do have the potential to increase the autonomy, independence, integration and quality of life of the elder users, and may positively impact on elder persons' welfare, they may also, at the same time, decrease their agency, impairing their liberty to choose whether or not to seek medical advice, whether or not to take their prescribed drugs, whether or not to follow a prescribed diet etc. In a word, there is a risk that AAL systems, through the ubiquitous medicalisation of life they may engender, replace traditional medical paternalism by techno-medical paternalism empowered with unprecedented means to record data about users' compliance with expected lifestyle, diet and behaviours (whereas the user's own subjective understanding of what constitutes a 'better, healthier lifestyle' is systematically disregarded as irrational).

In order to clearly identify the impact of AAL systems on users' autonomy, the conceptual distinctions between 'liberty of welfare' and 'liberty of agency' must be in place.[5] Relieving elder persons from choosing for themselves in a series of daily circumstances may indeed greatly ease their life and allow them to remain at home and live by themselves longer, but may decrease their sense of choice and agency, up to a stage where he doesn't feel any other alternative than complying with the 'rational' standards of lifestyle, diet, etc. given their diagnosed age, health status, disability etc.

3.3.1 Relevance to inCASA

The aims and objective of the inCASA project include enabling elderly citizens to live healthier, longer and more independently at home by using assistive and monitoring technologies and devices. As pointed out above, the flipside of these aims and objective is the risk of eroding the individual's autonomy. End-users must be explained to full the consequences (in relation health as well as technological) of both compliance and non-compliance with their individual use cases/care plans for inCASA. This will be secured through the process of obtaining informal consent from all end-users, as well as by considering the questions defined in the check list below.

3.3.2 Check List

- Does the project curtail a person's right to liberty and security in any way?
- Does the project recognise and respect the right of persons with disabilities to benefit from measures designed to ensure their independence, social and occupational integration and participation in the life of the community?
- Will the project use a technology to constrain a person or curtail their freedom of movement or association?

3.4 Dignity

The concept of human dignity is a cornerstone of the EU constitutional architecture. The European Charter of Fundamental Rights affirms this in Article 1: "Human dignity is inviolable. It must be respected and protected." [1]

The principle of dignity affirms that any human being is priceless, literally invaluable, independent of their age, gender, socio-economic condition, ethnicity, religion, etc. According to the Charter, dignity includes i) the right to life and ii) the right to the integrity of the person, which also implies the right to the free and informed consent of the person concerned. These two aspects are very relevant in the context of healthcare and assistive ICT. These technologies may offer a way to extend senior citizens' lives (particularly those living with a chronic illness) in a more comfortable, more dignified condition. The right to the integrity means that one's physical and psychological conditions should be respected and no one has the right to infringe upon them without explicit and informed permission. This principle holds true also for senior citizens and is vital when one considers assistive technologies destined to meet the needs of senior citizen.

In this respect, it is vital that senior citizens, as end-users, are properly consulted so that their needs and requirements are met; so that solutions become individualised. In addition, as noted above, the end-user should be able to control the system or the devices in some way to prevent a complete erosion of autonomy and privacy. This includes the option of opting completely out (at any time) in relation to the use of assistive and/or healthcare technologies. It is important though to ensure that the end-user really understands what the technology offers, its risks and benefits as this is a prerequisite for an informed choice, and for informed consent. Involving the end-user to identify the needs and requirements of an ICT based system or service is a first step in the right direction.

[5] On that distinction, see Amartya Sen, Rights and Agency in Consequentialism and Its Critics (Oxford Readings in Philosophy), Scheffler, S (ed.), Oxford University Press. See also Sen, A (1995) Inequality Reexamined, Harvard University Press.

3.4.1 Relevance to inCASA

The inCASA services and solutions will be personalised to fit the individual end-user's needs and requirements. This means that each end-user will be carefully consulted and individual care plans/use cases will be developed. Moreover, the prioritisation and consolidation of user requirements will be done iteratively, thus allowing for any necessary modifications to be done. The pilots are also divided into two phases in order to benefit from real user experience with the inCASA enabled services and applications.

End-users who will participate in inCASA will be carefully selected by the pilot sites who will also provide sufficient information about the project. The selection process will differ between pilots but overall end-users will be selected not only on basis of health and care needs and criteria but also on their ability to fully understand what the pilot (including the technologies and applications) involves and requires from them. Informed consent forms will be obtained from all end-users, including information on how to opt out of the pilot (see 3.5.2).

3.4.2 Check List

- Does the project recognise and respect the right of citizens to lead a life of dignity and independence and to participate in social and cultural life?
- Is such recognition explicitly articulated in statements to those involved in or affected by the project?
- Does the project comprise or violate human dignity? For example, does the project involve body scanners?
- Does the project require citizens to use a technology that marks them in some way as cognitively or physically disabled?
- Does the project or service or application involve implants?

3.5 Informed Consent

In the context of healthcare technologies as exemplified above, an important step to overcome the ethical problems related to privacy and data protection and surveillance and autonomy is informed consent. Informed consent allows the user/patient to exercise control over his/hers personal data by determining who has access to what information and when.

Thus, it is crucial that coherent and accurate information about how the technology works, including how data is gathered, processed, stored etc., and what risks are involved with using the technology is provided in a non-jargon language. Here we need to consider that senior citizens are generally less technology-savvy and it is therefore difficult to predict the extent to which they may be able to fully understand the technical implications of such systems, e.g. without a firm grounding in the underlying principles of technology that engineers take for granted (wireless signals, sensor collection devices, databases). Obtaining informed consent from end-user should therefore include the possibility of allowing questions and answers for further clarification purposes if so needed.

Moreover, in order for informed consent to have any real effect, it is also necessary that the technology itself has the appropriate security measures built in to ensure that only those granted access by the user has access to the specified information. The technology should also be designed in a way that takes into account that not all users will grant the same level of access to their personal information. This will obviously affect the nature of the service on offer which the technology should be able to support and subsequently adapt to.[6]

One of the key conclusions from the "Bled Exploration of issues and guidance" on Ethics and e-Inclusion: Contribution to the European e-Inclusion Initiative reads: "Informed consent is vital, choices available must be understandable and transparent. They should be adapted to match the

[6] This leads us to another dimension of informed consent namely that the user should have to option of opt out from using a specific ICT service without loosing the right to healthcare; there must always be alternatives available.

comprehension level of the recipient. Consideration needs to be given to the right not to know". [19]

It is also important that users are informed of any potential risks by using a certain technology. However, informed consent from the user does not cancel out the issue of reliability or liability; it should be clearly stated who is liable if technology enabled service, e.g. a self-management system, monitoring or surveillance technologies etc., fails partly or completely.

In relation to healthcare and/or assistive technology one may envision cases where the user/patient is unable to give informed consent. Take the example of people with dementia who are unlike to fully understand how a monitoring system capture and transmit information and the kind of information in question. If users cannot fully understand, or are unaware of, how a system or devices function, they may also not understand or be fully aware of how their privacy might be affected. Informed consent must then be given by the user/patient's guardian or other trustee.

3.5.1 Relevance to inCASA

As inCASA's end-users are elderly people (65+) and involves innovative information and communication technologies, it is crucial that the end-users (the elderly) are given detailed and easy to understand information (in a lay-man language) about the project, the technology, the applications and devices and how they will be used. In addition, as the pilots involve the transmission and analysis of personal and medical data, end-users might have concerns about data protection and privacy issues. They must therefore be given every opportunity to raise these concerns and ask questions. Each pilot is committed to do so as part of their recruitment process and informed consent forms will be obtained from all end-users. The Ethical Board will obtain a copy of all the informed consent forms.

3.5.2 Check List

Ethical questions in relation to informed consent include:

- Has the project obtained the free and informed consent of those persons involved in or affected by the project?
- Has the person been informed of the nature, significance, implications and risks of the technology in question?
- Has such consent been evidenced in writing, dated and signed, or otherwise marked, by that person so as to indicate his consent?
- If the person is unable to sign or to mark a document so as to indicate his consent, has his consent been given orally in the presence of at least one witness and recorded in writing?
- Are people aware that personal data may be collected? Are they aware of who is collecting it and why?
- Has the person consented to collection of his personal data?
- Does the consent outline the use for which data are to be collected, how the data are to be collected, instructions on how to obtain a copy of the data, a description of the mechanism to correct any erroneous data, and details of who will have access to the data?
- If the individual is not able to give informed consent (because, for example, the person suffers from dementia) to participate in a project or to use of a technology, have the project representatives consulted with close relatives, a guardian with powers over the person's welfare or professional carers? Has written consent been obtained from the patient's legal representative and his doctor?
- Has the person had an interview with a project representative in which he has been given the opportunity to understand the objectives, risks and inconveniences of the project or research activity and the conditions under which it is to be conducted?

- Has the person been informed of his right to withdraw from the project or trial at any time, without being subject to any resulting detriment or the foreseeable consequences of declining to participate or withdrawing?
- Has the project ensured that persons involved in the project have given their informed consent, not only in relation to the aims of the project, but also in relation to the *process* of the research, i.e., how data will be collected and by whom, where it will be collected, and what happens to the results?
- Are persons involved in or affected by the project able to withdraw from the project *and* to withdraw their data at any time right up until publication?
- Is consent given truly voluntary? For example, does the person need to give consent in order to get a service to which there is no alternative?
- Does the person have to deliberately and consciously opt out in order *not* to receive the “service”?

4 EU Policies and Directives Addressing Ethics

The main EU and international policy documents that are relevant to inCASA are briefly described here. Most of these have already been described and their relevance in relation to inCASA has been defined in D2.1 Preliminary requirements investigation. The purpose of mentioning these policies and directives here again, is to stress their relevance to inCASA's Ethical Guideline. Thus, the Ethical Board will oversee that the inCASA partners and in particular the running of the pilots will act in accordance and compliance with these policies and directives.

4.1 Charter of Fundamental Rights of the European Union

The following articles are particularly relevant to inCASA:

Article 3 Right to the integrity of the person

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

Article 7 Respect for private and family life:
Everyone has the right to respect for his or her private and family life, home and communications

Article 8 Protection of personal data:
Everyone has the right to the protection of personal data concerning him or her. 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. Everyone has the right of access to data which has been collected concerning him or her, and the right to have it rectified. Compliance with these rules shall be subject to control by an independent authority. [1]

4.2 European Convention for the Protection of Human Rights and Fundamental Freedoms

The European Convention for the protection of Human Rights and Fundamental Freedoms (ECHR) [16] of 1950 which formed the European Court of Human Rights provides a very high protection of the individual. The ECHR provides the legal background for the development of specific legislation to protect the interest of the citizen when ICT is used in healthcare. Article 8 of the ECHR, on privacy, is very relevant for inCASA, e.g. regarding protection of personal data:

1) Everyone has the right to respect for his private and family life, his home and his correspondence.

2) There shall be no interference by a public authority with the exercise of this right except such as is in accordance with the law and is necessary in a democratic society in the interests of national security, public safety or the economic well-being of the country, for the prevention of disorder or crime, for the protection of health or morals, or for the protection of the rights and freedoms of others.

4.3 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

The Directive identifies a set of fair information practices or principles which are important in any consideration of ethical issues that might arise in matters affecting privacy and data protection. The Directive is important in relation to ICT. For example, Article 14 reads: ”Whereas, given the importance of the developments under way, in the framework of the information society, of the techniques used to capture, transmit, manipulate, record, store or communicate sound and image data relation to natural persons, this Directive should be applicable to processing involving such data.” [18]

4.4 Directive 2000/58/EC concerning the processing of personal data and the protection of privacy in the electronic communications sector (Directive on privacy and electronic communications)

This Directive refers back to the Charter of fundamental rights of the European Union, stating that it ”seeks to ensure full respect for the rights set out in Articles 7 and 8 of that Charter.” The Directive aims to ensure “…in particular the right to privacy, with respect to the processing of personal data in the electronic communication sector and to ensure the free movement of such data and of electronic communication equipment and services in the Community.” [20]

4.5 Convention for the Protection of Individuals with regard to Automatic Processing of Personal Data of the Council of Europe of 1 January 1981

The objective of the convention is “to strengthen data protection, i.e. the legal protection of individuals with regard to automatic processing of personal information relating to them. There is a need for such legal rules in view of the increasing use made of computers for administrative purposes. Compared with manual files, automated files have a vastly superior storage capability and offer possibilities for a much wider variety of transactions, which they can perform at high speed. Further growth of automatic data processing in the administrative field is expected in the coming years *inter alia* as a result of the lowering of data processing costs, the availability of "intelligent" data processing devices and the establishment of new telecommunication facilities for data transmission.” The convention also takes the increasing trans-border flow of personal data into account. [21]

4.6 Directive 2002/58/EC on data protection

The development of ICT raises some specific requirement issues to ensure the users’ right to privacy and protection of data. Directive 2002/58/EC of the European Parliament and of the Council of 12 July 2002 concerning the processing of personal data and the protection of privacy in the electronic communications sector identifies various requirements that must be met for user to trust electronic communication services. Of particular relevance to inCASA, the Directive states that the provider of an electronic communications service must protect the security of its services by: 1) ensuring that personal data is accessed by authorised persons only; 2) protecting personal data from being destroyed, lost or accidentally altered; and 3) ensuring the implementation of a security policy on the processing of personal data. [22]

4.7 Declaration of Helsinki

The World Medical Association has identified a number of ethical principles for medical research involving human subjects, including research on identifiable human material and data. A few of these are worth highlighting here as they are particularly relevant to inCASA:

- Although the Declaration is addressed primarily to physicians, the WMA encourages other participants in medical research involving human subjects to adopt these principles.
- It is the duty of physicians who participate in medical research to protect the life, health, dignity, integrity, right to self-determination, privacy, and confidentiality of personal information of research subjects.
- In medical research involving human subjects, the well-being of the individual research subject must take precedence over all other interests.
- Medical research is subject to ethical standards that promote respect for all human subjects and protect their health and rights. Some research populations are particularly vulnerable and need special protection. These include those who cannot give or refuse consent for themselves and those who may be vulnerable to coercion or undue influence.
- Every precaution must be taken to protect the privacy of research subjects and the confidentiality of their personal information and to minimize the impact of the study on their physical, mental and social integrity. [4]

5 National Authorisation and Regulation Principles

In addition to EU and international regulations, it is vital to be aware of any specific national authorisation and regulation principles and laws in relation to the execution of the pilots. This includes examining whether formal approval from the local ethical committee is necessary. Each pilot is responsible for ensuring that they uphold the relevant legal administrative requirements and obtain the required authorisations and approvals. This will be checked by the Ethical Board. The following section provides an overview of the relevant national laws, authorisation and regulations in each pilot country.

5.1 Italy

The main legal and deontological frame to be taken in account and referring to the activities are the following ones:

ACT 31.12.1996 n. 675
As amended by Legislative Decree no. 123 of 09.05.1997, no. 255 of 28.07.1997, no. 135 of 08.05.1998, no. 171 of 13.05.1998, no. 389 of 6.11.1998, no. 51 of 26.02.1999, no. 135 of 11.05.1999, no. 281 of 30.07.1999, no. 282 of 30.07.1999 and no. 467 of 28.12.2001, followed by DLGS 30 giugno 2003, n. 196, so called “Codex for the protection of personal data**, updated** several times, sometimes to follow EU recommendations.

Generally speaking, Italian laws regards privacy includes the European Directive, starting from 1995, and provides that personal data are to be processed "by respecting the rights, fundamental freedoms and dignity of natural persons, in particular with regard to privacy and personal identity". Thus, privacy becomes a fundamental component of the "electronic citizenship" which will be a basic feature in the 21st century. This target cannot be achieved solely through an Act ensuring a high level of protection to citizens: powerful social legitimisation is also required.

The level of protection ensured by the Italian law is considerable. This is partly due to the fact that Parliament chose to include, from the very beginning, significant provisions of the EU Directive into domestic legislation; hence, the protection of personal data processed in Italy is, at least currently, in many instances greater than that ensured by countries in which this is long-standing practice.

Social legitimisation also results from the fact that the supervisory authority is direct, exclusive expression of Parliamentary activity. The four members of the Supervisory Authority for Personal Data Protection are elected by both Houses, and the chairman is, in turn, elected by the members. This means that no undue pressure 1s exercised by Government, which obviously enhances the independence of the authority. Further, being directly linked to popular sovereignty - through the election by Parliament - the authority is especially qualified to carry out activities which are aimed, firstly and above all, at protecting values and fundamental rights to which all citizens are entitled.

Thus, the Garante (the “guarantor”) is not entrusted exclusively with the task of monitoring or auditing data hanks: in fact, it has considerable power of action, including data hanks to which no supervision usually applies (see for instance Act 675, Article 4). This is the case, for instance, of intelligence services, which may not dismiss the requests made by the Garante on grounds of State secrecy - as is often the case in respect of similar requests made by judicial authorities.

The Garante is also committed the difficult task of striking a balance between diverging interests. This is apparent as regards the relationships between privacy and freedom of the press, hut also applies to other matters - such as sensitive data; processing of such data is allowed only with the data subject's consent and with the authorization by the Garante.

Act no. 675 is accompanied by another Act (no. 676) which provides flexibility and can be said to be a gateway to the future. Self-amendment arrangements are provided for: based on the experience gained in the implementation of the Act, the Government may issue decrees

supplementing and/or amending the Act so as to bring the latter fully into line with actual requirements. Two such decrees have already been issued. Furthermore, the Government was enabled to issue, since by the end of 1998, a number of decrees which should allow supplementing the existing legislation in especially complex areas or in sectors showing innovations due to the development of information and communication technology. This entails the commitment towards laying down provisions applying to the whole issue of telematics networks by the term stated - which will prevent leaving out the very sectors in which the protection of fundamental human rights is especially necessary and involves a greater effort.

In general, the criteria for collecting personal data, which is relevant for inCASA, are as follows:

1) processed lawfully and fairly;
2) 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;
3) accurate and, when necessary, kept up to date;
4) adequate, relevant and not excessive in relation to the purposes for which they are collected or subsequently processed;
5) 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.

Processing of personal data for historical, scientific research or statistics purposes shall be consistent with the purposes for which the data are collected or subsequently processed and may be carried out even after expiry of the period that is necessary for the latter purposes.

Furthermore, regarding the way the data are collected:

1. The data subject as well as whoever is requested to provide personal data shall be preliminarily informed, either orally or in writing, as to:
    - the purposes and modalities of the processing for which the data are intended;
    - the obligatory or voluntary nature of providing the requested data;
    - the consequences if he fails to reply;
    - the subjects or the categories of subjects to whom the data can be communicated and the area within which the data may be disseminated;
    - the rights as per article 13;
    - the name, denomination or trade name and the domicile, residence, or registered office of the controller, the controller's representative on the State's territory and at least one data processor, the latter being the entity referred to for the purposes set out in Article 13, by specifying either the site in the communications network or the mechanisms for accessing, without constraint, the updated list of data processor.

Regarding personal data allowing the disclosure of racial or ethnic origin, religious, philosophical or other beliefs, political opinions, membership of parties, trade-unions, associations or organizations of a religious, philosophical, political or trade-unionist character, as well as of health conditions and sex life, they may be processed only if the data subject gives his consent in writing, subject to authorization by the Garante. A similar strong protection is given to medical data. Health professionals and public health institutions may process, even without being authorised by the authorities, personal data disclosing health exclusively with regard to the data and operations required in order to safeguard the data subject's bodily integrity and health. Where the selfsame purposes concern a third party or the public as a whole and the data subject fails to give his consent, the data may be processed upon authorization by the Garante.

The matter of scientific, medical and statistic data collection is also focussed on by the “Code of conduct and professional practice applying to the processing of personal data for statistical and scientific research purposes within the framework of the national statistical system” *(Published in the Official Journal no. 230 of October 10, 2002)*. This document will be consulted for any relevance to inCASA.

Last but not least, each public body has a Code of Behaviour of the Public Officer that follows the guidelines of the national Code for Public Administration. Among other things, this obliges the employees to follow general rules of fairness and respect for the citizens. Both ATC and Municipality of Torino have a Code of Behaviour of the Public Officer.

With reference to the following Agreements between the Municipality of Turin and the Local Health Board Authorities DGR 51-11389 23 December 2003 and DPCM of the 29 November 2001 (Law 328) an ethical approval from an ethical committee or other authority it is not required for the ATC pilot.

National Ethics Committee: http://www.palazzochigi.it/bioetica/

5.2 Spain

Spanish Organic Law 15/1999 of 13 December on the Protection of Personal Data (LOPD 15/1999). Specially the legislation concerning the following articles:

- Art. 4: Quality of the data
- Art. 5: Right of information in the collection of data
- Art. 9: Data security
- Art 10: Duty of secrecy
- Art. 15: Right of access
- Art. 16: Right of rectification or cancellation

Other relevant laws include:

- 14/1986 General Health Care Law
- 41/2002 patient autonomy Law
- 16/2003 Cohesion and Quality Law
- 2/2002 Health of La Rioja Law

Approval must be sought by the ethical board CEICLAR[7] (regulated by 71/2005 decree).

National Ethics Committee: http://www.comitedebioetica.es/?lang=en_US

5.3 UK

In England, review by an ethics committee is one of a series of safeguards intended to protect the people taking part in the research. Research Ethics Committees (RECs) review applications for research and give an opinion about the proposed participant involvement and whether the research is ethical. The RECs are completely independent of research sponsors (that is, the organisations funding and hosting the research) and investigators. This enables them to put participants at the centre of their research. Each year, RECs in England review around 6,000 research applications. On average, they give an opinion after 35 days: well within the maximum allowance of 60 days.

The REC safeguards are set out in a series of documents and guidance[8]:

- Declaration of Helsinki (World Medical Association, as amended 2008)[9]:
  Sets out ethical principles for medical research involving human subjects, including research on identifiable human material and data.

[7] http://www.cibir.es/cibir-investigacion/ceiclar
[8] http://www.nres.npsa.nhs.uk/aboutus/protecting-participant-safety/
[9] http://www.wma.net/en/30publications/10policies/b3/index.html

- Research Governance Framework for Health and Social Care (2nd edition) (Department of Health, published 24 April 2005)[10]:
  Establishes a framework for the governance of research in health and social care. It applies to all research that relates to the responsibilities of the Secretary of State for Health (that is, research concerned with the protection and promotion of public health, research undertaken in or by the Department of Health, its non-departmental public bodies and the NHS), and research undertaken by or within social care agencies.

  It includes clinical and non-clinical research; research undertaken by NHS or social care staff using the resources of health and social care organisations; and any research undertaken by industry, charities, research councils and universities within the health and universities within the health and social care systems that might have an impact on the quality of those services.

- Governance Arrangements for NHS Research Ethics Committees (GAfREC) (Department of Health, published July 2001)[11]
  Provides a standards framework for the ethical review of all NHS and social care research proposals which is efficient, effective and timely, and which will command public confidence. It sets out general standards and principles for an accountable system of Research Ethics Committees (RECs) working together to shared high standards of review and operating process throughout the NHS. It should be read in conjunction with the Research Governance Framework for Health and Social Care, above.

On the following page a flowchart is detailing the process of gaining ethical approval for the inCASA project in England.[12]

[10] http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4108962

[11] http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4005727

[12] http://www.nres.npsa.nhs.uk/applications/guidance/trials-and-procedure-flowcharts/?esctl1507899_entryid62=67034

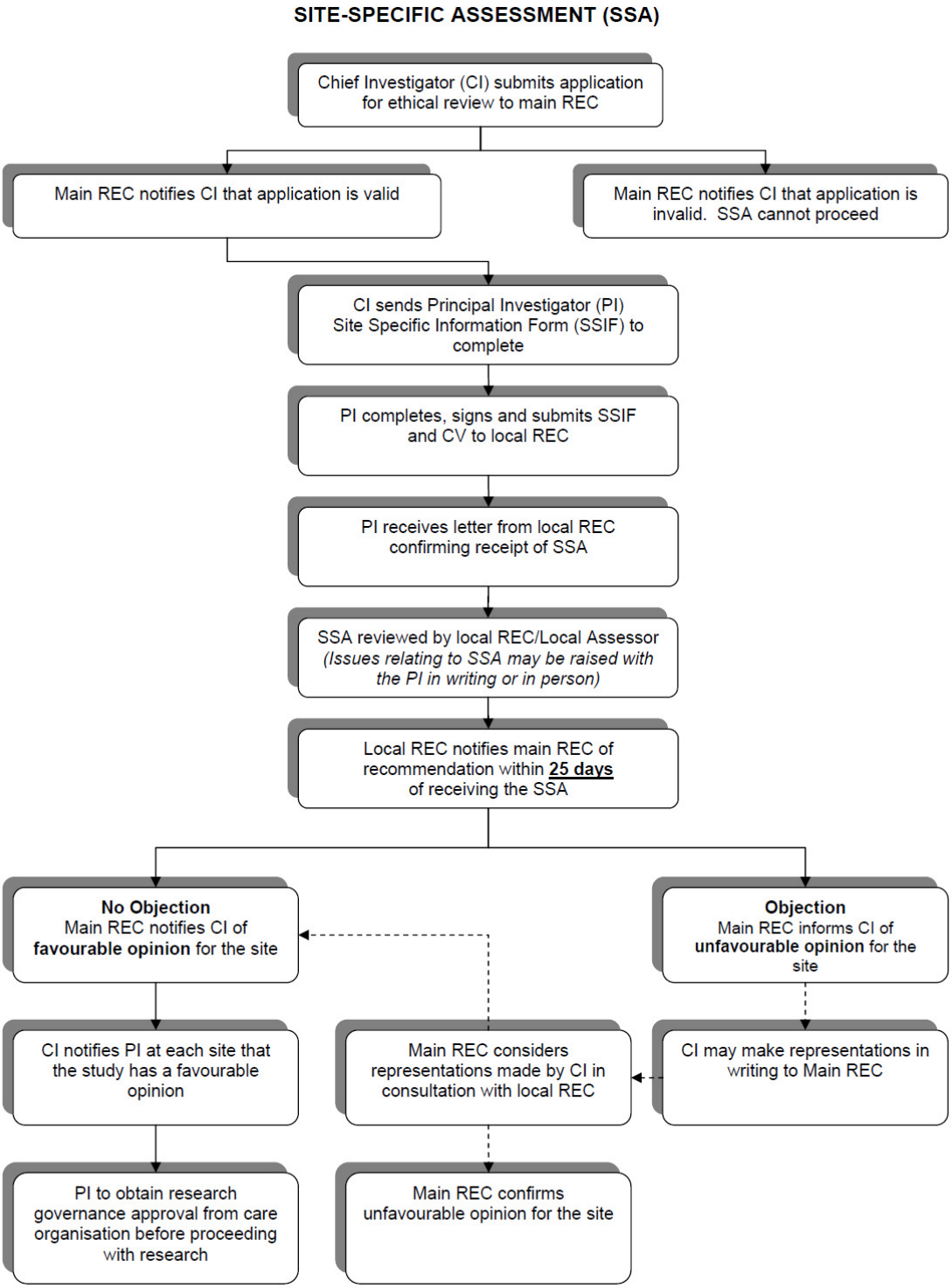

Figure 1: Procedure for ethical approval

National Ethics Committee: http://www.hfea.gov.uk/cps/rde/xchg/hfea/

5.4 France

The law governing the human research in France is a modification of the Hurriet law:

Act No. 2004-806 of 9 August 2004 concerning the public health policy (including amending the Huriet law on biomedical research, integrated for this part in the Public Health Code, Articles L.

1121-1 et seq) OJ French Republic on 11 August 2004[13]. This law descirbes, among other, two typical categories of clinical research on humans: interventional and non-interventional (see Figure 1).

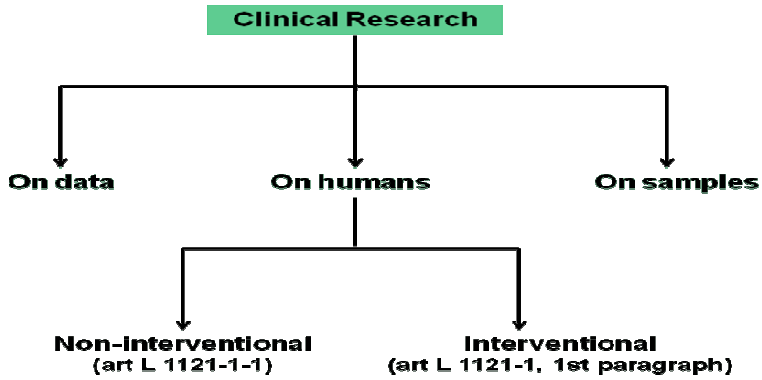

Figure 2: Act No. 2004-806 regarding clinical

However, in this law it is specified that non interventional research like the French inCASA pilot (non invasive, observational) does not need a decision of approval from the Committee on Protection of Individuals. The ethical committee may be asked for advice and the French pilot (INSERM) will therefore do so.

The French pilot will also prepare an information form and an informed consent form that will be presented to the patients during the inclusion visit (please refer to Appendix D for a possible informed consent from that we could present to the patients). The information form will be done when we will be sure of all of the data that we can collect from the patients.

The gathering, encryption and coding of data comes under the law of “loi informatique et libertés 1978-1994-2004”. Indeed, this law concerns the treatment of personal data with the purpose of research in the field of health (Act July 1994). Thereby, we have to declare that we will treat personal data of the patients to the committee “Comité National de l’Informatique et des Libertés (CNIL)”.

National Ethics Committee: http://www.ccne-ethique.fr/

5.5 Greece

All the medical trials or studies in Greece should be approved by the local Ethical Committee of the hospital in which the study is running. After this, the final approval should be given by the Regional Health Authority of Attica Greece. The pilot in Greece (KGHNI) will apply for approval as required.

In addition, the Greek pilot will prepare an information form and an informed consent form that will be presented to the selected patients during the inclusion visit.

Individual protection for personal data processing - 2472/1997 Greek law
Hellenic Data Protection Authority (2000)

National Ethics Committee: http://www.bioethics.org.gr/en/

[13] www.legifrance.gouv.fr

6 Informed Consent Process

Informed consent is the process by which a participant will be fully informed about the research in which he/she is going to participate. It originates from the legal and ethical right that the participant has to direct what happens to his/her personal data and from the ethical duty of the researcher to involve the participant in the research. This means that the subject has the right to be involved in the research process.

The inCASA pilots are obliged to collect informed consent from all the participants (the end-users) to ensure that they fully understand the project and what they as participants are agreeing to participate in and what rights they have as participants. The pilots may use their own official informed consent form (examples can be found in Appendix C and D), or they may use the standard inCASA informed consent form which can be found in Appendix B. In the case of the latter, pilots will, however, need to translate the form into their local language.

As noted above, the pilots must explain carefully what the pilot and the project entails before participants (end-users) sign the informed consent form. To do so, it is useful to look at the pilot from the end-user's perspective, i.e. to think of the possible questions or concerns end-user might have and use this as a guideline for the issues and questions that should be made clear to the end-user. Of course, end-users must also be allowed to ask additional clarifying questions or raise additional concerns which the pilots must answer as best as possible.

The original informed consent forms will be kept by the pilots whereas participants will receive a copy. In addition, a written statement confirming that the participant has received proper information about the pilot before signing the informed consent form will be signed by the pilot (see Appendix E), and finally, a record of the participant's identity and reference number from the participant stating that informed consent has indeed been given will also be kept (see Appendix F). Copies of these two statements may be forwarded to the inCASA Ethical Board upon request.

Below is a list of issues (as seen from the end-user's perspective) that pilots should explain to end-users before they sign the informed consent form and thus prior to the pilot's start:

1. Title / reference of the pilot

2. What is the purpose of this pilot?

3. You are asked to take part in a pilot under the direction of _____. Other professional persons who work with him/her may assist or act for them. These investigators are undertaking pilot study to determine whether _____. We expect to find _____, which could lead to better methods of diagnosis / treatment / monitoring.

4. Who can take part in this pilot?

5. Why should I consider joining this pilot as a research participant?

6. Do I have to become a participant in this pilot? If I joined the pilot, can I change my mind and drop out before it ends?

7. What exactly will be done to me, and what kinds of treatments or procedures will I receive, if I agree to be a research participant in this pilot?

8. What kinds of harm can I experience in this pilot, and what will the investigators do to reduce the chances of harm?

9. What will the investigators do to make sure that the information they will collect on me will not get in the wrong hands?

10. What kinds of benefit can I expect personally from taking part in this pilot?

11. What kinds of benefit to others can come out of this pilot?

12. What will the investigators do, if I get injured in the pilot?

13. Will I get paid for taking part in this pilot?

14. Will I or my health insurance company be charged for any of the costs of this pilot?

15. Once I start in this pilot as a participant, what do I do if I want to find out more about the pilot/project, or to complain about the way I get treated?

16. Who gets to keep this document, once I sign it?

17. Which others may view or use the data of this document, if any?

7 inCASA Ethical Policy

The inCASA Ethical Policy has been established to set standards regarding the way inCASA partners should operate in ethical matters, particularly in relation to the execution of the inCASA pilots as these will involve elderly frail people.

The inCASA Ethical Policy have been implemented in a set of Ethical Guidelines which directs the practical work and sets out how partners shall address the ethical issues and which questions should be asked before and during pilot execution. The Ethical Guidelines have been defined in the deliverable D2.3 National country policies and ethical package and are subject to approval by the inCASA Ethical Board.

The Ethical Policy helps define the inCASA project's commitment to ensure a working culture based on trust, integrity and transparency and to carry out all project activities with the highest standards of ethical conduct.

A main objective of the Ethical Policy is to protect the rights of the patients and residents that will participate in the inCASA pilots.

As additional issues are likely to appear as the project advances, the Ethical Policy will be reviewed on a yearly basis.

The inCASA Ethical policy contains 10 principles that will ensure that the consortium conducts ethically responsible pilots:

1. Respect the right to privacy and protection of data of all participants in the project and the pilots.
2. Respect the right to autonomy of all participants in the project and the pilots.
3. Respect the right to dignity of all participants in the project and the pilots.
4. Be committed to transparency and integrity when ethical issues arise.
5. Respect and abide with international, European, national and local legal and ethical requirements.
6. Obtain ethical approval from national ethical committees as required in relation to the execution of the pilots.
7. Obtain written informed consent from all participants in the pilots.
8. Adhere to the Ethical Guidelines set out in D2.3 National country policies and ethical package.
9. Report all ethical issues encountered before and during the pilot execution to the inCASA Ethical Board for further consideration, without any delay.
10. Address all questions related to ethical issues raised by the Ethical Board without any delay.

8 inCASA Ethical Board Terms of Reference

In order to ensure that the inCASA project is ethically sound an Ethical Board has been created. The inCASA Ethical Board is the highest authority on ethical matters in the inCASA project, only subject to mandatory EU, national and institutional ethical principles and regulations. This chapter describes the terms of reference for the inCASA Ethical Board. It thus includes a description of the Ethical Board's objectives, composition, working procedures and what should be reviewed. A brief background description of the inCASA project is also included as this chapter in effect should be able to stand alone as the inCASA Ethical Board Terms of Reference.

8.1 Background

The inCASA project will develop citizen-centred technologies and a service network to help and support frail elderly people. The goal is to enable elderly people to live longer and healthier in their own home by:

- Providing the means to profile the everyday behaviour of elderly people in their own home, through unobtrusive monitoring using motion and contact sensors, as part of a Smart Personal Platform with embedded Behaviour Analysis, to determine unusual behaviour and send alerts via a base station to selected actors

- Providing elderly people (and patients with special needs) with the means to monitor their health conditions outside traditional healthcare environments, and more specifically while they are at home, by using state of the art personal health systems and integrated telemedicine services

- Providing doctors and health professionals with more comprehensive monitoring data to understand the social, physical and/or psychological condition of the person and so allow early decision for personalised care.

The inCASA project includes five pilot sites (in five different countries) which will each select 30-40 of their users to participate in the inCASA project. The users will be elderly people with chronic health conditions and/or frail people living alone who need some level of home assistance, care or support.

Each pilot site will manage their pilot/project on an individualised basis in order to reflect the national differences in the way that social and healthcare services are organised, as well as the diverse needs and expectations of the different user communities, service types, institution types, and finally the differences in local legal frameworks.

As the inCASA project involves human beings in the research and testing of the project ethical approval is necessary. The pilots will therefore as necessary submit their study protocol to their national ethical committee for approval. The pilots will be performed according to guidelines of the national ethical committees. In addition, the inCASA project has decided to establish a project Ethical Board specifically for the project and the pilot sites.

8.2 Objectives and Composition of the Ethical Board

Ethical Board means the individuals who will assess the compliance of the pilots to inCASA's Ethical Guideline. The Ethical Board will be active throughout the duration of the inCASA project.

The inCASA Ethical Board main objective is to ensure that the inCASA project, including the pilot sites, is ethically sound, thus safeguarding the privacy, dignity, data security, access, informed consent, and user information of all actual or potential project research and testing participants.

Thus, the Ethical Board must always act to protect the rights of the pilot participants (i.e. patients/residents). To achieve this end, the Ethical Board will monitor that the pilots comply with national ethical principles (i.e. that any necessary approval from national/local ethical committees have been obtained) and that the pilots do not cause any violation or risk to the participants' privacy, autonomy and dignity, particularly as the surveillance/monitoring technologies that will be employed may threaten the individual's privacy, autonomy and dignity. Moreover, the Ethical Board will assess whether the necessary data protection measures are in place. In practice this means that the Ethical Board will review the project deliverables (particularly WP6 Pilot Use Cases).

Furthermore, the regular contact and reporting (e.g. conference calls) between project partners should ensure that any unforeseen ethical issues will come to the attention of the Ethical Board who will then take the appropriate measures (e.g. consult with the pilot to seek a solution, see below). This continuous assessment throughout the running of the pilots will ensure that the pilots comply with international and national ethical standards.

The Ethical Board will tackle any ethical issue concerning privacy of the patient and user information, including the security of the obtained medical information (inCASA Description of Work, DoW, p. 101). The Ethical Board will thus act as both an evaluator and advisor for project partners, if and when any ethical concerns in relation to the project appear, and in cooperation with the relevant project partner(s) come up with a way to resolve the issue at hand and define a way forward.

The Ethical Board's first official action was to define and agree upon the project's Ethics Policy (presented in Chapter 7) at the first general assembly meeting which was held in Rome, 11-12 April 2011.

Composition
The Ethical Board will consist of a Chair and at least four permanent members: three members with clinical expertise and one lay member. The permanent members will be representatives from the different pilot sites. Members must be both men and women.

The members who have been selected to sit on the inCASA Ethical Board are:

- Trine Fuglkjær Sørensen (Chair) – INJET
- Russell Jones – CHC
- Garance Dispersyn – INSERM
- Pelayo Benito – FHC
- Gianfranco Tarabuzzi – ATC

In addition, up to two external experts may be invited and consulted as necessary. The external experts should have expertise in at least one of the following areas:

- Ethical issues
- Elderly & ICT
- Legal issues and human rights

The Chair and the members have been (are) appointed by consensus by the inCASA consortium. The external experts are proposed by the Chair and subject to acceptance by the inCASA consortium.

8.3 Activities and Methods

The Ethical Board will assist project partners to identify ethical issues and how to deal with these. Thus, the Ethical Board is responsible for advising project partners as required to ensure that procedures are implemented and conducted correctly, and for ensuring that the pilot sites adhere to the project's Ethical Policy.

This also means that the Ethical Board may intervene as necessary if it judges that i) there is a potential ethical issue arising which requires attention or ii) if a pilot is not complying with the project's Ethical Guideline.

If a violation of the Ethical Guideline or of a participant's rights is at stake as a result of the running of a pilot, and cannot be resolved within the pilot, the Ethical Board may request that the pilot is temporarily stopped until the matter is resolved.

The Ethical Board will also be available per demand meaning that should a project partner have any ethical concerns in relation to the project, they may contact the Ethical Board in writing stating the nature of the concern and its potential consequences for the project. The Ethical Board will subsequently consult the project's Ethical Guideline defined in this document as well the relevant national and international regulations (if necessary), in order to determine the nature of the issue and propose a resolution.

The Ethical Board will always strive to find a resolution that is acceptable and/or feasible for the project partner in question and will therefore consult with the project partner before a resolution is finally determined. In addition, in particular complex situation, the Ethical Board may want to consult with external experts. This may also be the case if the Ethical Board cannot agree on a solution. The Ethical Board will, however, have the final say as determined in the inCASA project's Description of Work (p. 107).

The Ethical Board will deal with any ethical issues that may affect or concern the project partners:

- **Ensure that all partners adhere to the inCASA Ethical Guideline** (DoW, p. 106)
  - All assessment tools and protocols used within inCASA pilots will be verified beforehand by the Ethical Board to determine their impact on the users' well-being (DoW, p. 106);
  - The Ethical Board will review any document intended for public publishing prior to its publishing;
  - As part of internal review of project deliverables, the Ethical Board will check that deliverables are in line with the project's Ethical Guideline (DoW, p. 107);
  - The Ethical Board will review the project's Ethical Guideline at least once a year and changes will be communicated to the project consortium for agreement prior to their submission to the European Commission (DoW, p. 106).

- **Ensure that pilots fulfil national ethical requirements** (DoW, p. 106 & 116)
  - The pilot sites are responsible for the timely submission to the Ethical Board of a copy of their application (study protocol) to their national ethical committee. The Ethical Board will check the application prior to its submission to the national ethical committee (DoW, p. 107). A copy of the obtained approval by the national ethical committee must be submitted to the Ethical Board prior to the pilot's start.
  - If approval by the national ethical committee is not required, the pilot site is responsible for submitting such statement from the national ethical committee or other authorities to the Ethical Board.

- **Ensure that pilots obtain informed consent (in writing) from each of the pilot participants** (DoW, p. 106)
  - D2.3 European country policies and Ethical package will include guidelines regarding obtaining informed consent from participants (see Chapter 6). The Ethical Board will be able to refer pilots site to these guidelines should questions arise regarding informed consent/informed consent forms.
  - The Ethical Board may ask pilots to confirm in writing that they have obtained informed consent from all their pilot participants before the pilot starts.

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Appendix A: Overview of the Ethical Guideline Check List

Privacy and Data Protection

- Is information collected in ways of which the data subject is aware?
- Will the information be deleted when it is no longer needed for the purpose for which it was collected?
- Who will have access to or use of the data collected?
- Will the data be transferred to or shared with others without the person's awareness?
- Has the project taken steps to ensure that persons cannot be identified from the data to be collected?
- What assurances exist that the information collected is true and accurate?
- Has the project taken measures to ensure protection of personal data, e.g., by means of encryption and/or access control? If so, what are they?
- Have measures been put in place to facilitate the person's access to his or her personal data?
- Can the person whose data are collected rectify easily errors in personal data? What procedures are in place for doing so?

Surveillance

- Have any signs or other notifications been made to alert people to the presence of CCTV cameras or other surveillance devices?
- How and for how long will images or data be retained?
- How will such images or data be used or erased?
- Who will authorise the surveillance practice, whether in private homes or assisted living residences?
- What measures will be put in place to avoid abuses where, for example, surveillants watch others engaged in behaviour that generally accepted social norms would regard as intimate or private?

Autonomy

- Does the project curtail a person's right to liberty and security in any way?
- Does the project recognise and respect the right of persons with disabilities to benefit from measures designed to ensure their independence, social and occupational integration and participation in the life of the community?
- Will the project use a technology to constrain a person or curtail their freedom of movement or association?

Dignity

- Does the project recognise and respect the right of citizens to lead a life of dignity and independence and to participate in social and cultural life?
- Is such recognition explicitly articulated in statements to those involved in or affected by the project?
- Does the project comprise or violate human dignity? For example, does the project involve body scanners?
- Does the project require citizens to use a technology that marks them in some way as cognitively or physically disabled?
- Does the project or service or application involve implants?

Informed Consent

- Has the project obtained the free and informed consent of those persons involved in or affected by the project?
- Has the person been informed of the nature, significance, implications and risks of the technology in question?

- Has such consent been evidenced in writing, dated and signed, or otherwise marked, by that person so as to indicate his consent?
- If the person is unable to sign or to mark a document so as to indicate his consent, has his consent been given orally in the presence of at least one witness and recorded in writing?
- Are people aware that personal data may be collected? Are they aware of who is collecting it and why?
- Has the person consented to collection of his personal data?
- Does the consent outline the use for which data are to be collected, how the data are to be collected, instructions on how to obtain a copy of the data, a description of the mechanism to correct any erroneous data, and details of who will have access to the data?
- If the individual is not able to give informed consent (because, for example, the person suffers from dementia) to participate in a project or to use of a technology, have the project representatives consulted with close relatives, a guardian with powers over the person's welfare or professional carers? Has written consent been obtained from the patient's legal representative and his doctor?
- Has the person had an interview with a project representative in which he has been given the opportunity to understand the objectives, risks and inconveniences of the project or research activity and the conditions under which it is to be conducted?
- Has the person been informed of his right to withdraw from the project or trial at any time, without being subject to any resulting detriment or the foreseeable consequences of declining to participate or withdrawing?
- Has the project ensured that persons involved in the project have given their informed consent, not only in relation to the aims of the project, but also in relation to the *process* of the research, i.e., how data will be collected and by whom, where it will be collected, and what happens to the results?
- Are persons involved in or affected by the project able to withdraw from the project *and* to withdraw their data at any time right up until publication?
- Is consent given truly voluntary? For example, does the person need to give consent in order to get a service to which there is no alternative?
- Does the person have to deliberately and consciously opt out in order *not* to receive the "service"?

Appendix B: inCASA standard Informed Consent Form

This consent form template can be used by pilots should they not have their own official consent form.

This part will be filled in by the participant.

The original will be kept be the investigator; a copy will be given to the participant.

Title of the study:_____

Place of the study:_____

	Please circle/cross as necessary	
I was informed about the effect to be expected, about possible disadvantages and about possible risks verbally and in writing by the test leader of the study.	**Yes**	**No**
I was informed about the purpose of research, the expected duration and the procedures verbally and in writing by the test leader of the study.	**Yes**	**No**
I was informed about any benefits to me or to others which may reasonably be expected from the research.	**Yes**	**No**
I was informed about the explanations on confidentiality (and limits) of the data.	**Yes**	**No**
I was informed about the right to decline to participate and to withdraw from the research once participation has begun and the foreseeable consequences of declining or withdrawing.	**Yes**	**No**
I was informed about whom to contact for questions about the research and research participants rights.	**Yes**	**No**
I have read and understood the written information handed out for the study mentioned above. My questions in connection with the study have been answered satisfactorily. I can keep the written information and receive a copy of my written declaration of consent.	**Yes**	**No**
I had sufficient time to take my decision.	**Yes**	**No**
In case an incident arises contrary to expectation, insurance consists for me in the legally specified scale. The insurance was constructed by …… for this study.	**Yes**	**No**

I have spoken to: Dr./Mr./Ms. …….		
I understand that I am free to withdraw from the study ♦ at any time ♦ without having to give a reason for withdrawing ♦ and without affecting my future medical care	**Yes**	**No**
I agree to take part in the study.	**Yes**	**No**
The confidentiality of my personal data was assured to me. Personal date will used anonymously at the publication of the studies results. I approve of the fact however under a strict compliance with the confidentiality that the responsible experts of the authorities and the ethics commission may take a look for examining and control purposes of my original data.	**Yes**	**No**
If after-effects appear, I will contact Dr./Mr./Ms. …….. with the tel. no. ……..		

Signed.....

Date.....

Name (in block letters) .....……

Appendix C: CHC Consent Form

CHORLEYWOOD HEALTH CENTRE
15 LOWER ROAD, CHORLEYWOOD
HERTFORDSHIRE, WD3 5EA
TEL: 01923 287100
FAX: 01923 28712

Patient Consent Form

Patient name:……

Project Title:……

I agree to participate in the Telehealth Service and I understand that as part of this service that:

- I confirm that I have read and understood the information sheet for the above service. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily
- The monitoring equipment is not an emergency response device. I understand that in case of immediate medical emergency, I know to call my General Practitioner (GP) or contact Emergency Services
- I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason and without my normal clinical care or legal rights being affected. I confirm that I will inform Chorleywood Health Centre within 3 working days of my decision to withdraw from the service.
- I understand that the monitoring equipment remains the property of Chorleywood Health Centre and that the monitoring equipment will be removed as directed by the clinical team at Chorleywood with 3 days working notice.
- I understand that the monitoring equipment is intended for my use only and any and all measurements that are transmitted should be mine.
- I understand that health data and information gathered about me via the monitoring equipment during the service will be shared with members of the health team at Chorleywood Health Centre. Furthermore sections of my medical notes may be looked at by individuals from Brunel University or from regulatory authorities where it is relevant to my taking part in service. I give permission for these individuals to have access to my records.

Patient signature _____ Date _____
Or
Carer's name _____

Carer's signature _____ Date _____

Name of Person Taking Consent _____

Signature of Person Taking Consent _____ Date _____

Appendix D: INSERM Consent Form

DOCUMENT D'INFORMATION ET DE CONSENTEMENT ÉCLAIRÉ
ETUDE XXXX XXX XXX

Identifiant du sujet : _____

Le Professeur/Docteur _____ vous propose de participer à une recherche biomédicale intitulée :
_____ .

Ce consentement est destiné à vous donner des explications sur cet essai et à recueillir votre consentement si vous désirez y participer.

Votre participation à cette étude est volontaire et vous n'êtes en aucun cas obligé d'y prendre part. Si vous refuser d'y participer pour quelque motif que ce soit, la qualité de vos soins n'en sera nullement affectée.

Si au cours de cette recherche, de nouvelles informations étaient disponibles, pouvant remettre en cause votre participation, le médecin chargé de cette recherche vous les communiquera et s'assurera que vous souhaitez continuer à y participer.

Même si vous consentez à participer, vous pourrez ensuite interrompre votre participation à l'étude à tout moment ; mais pour votre sécurité, nous vous demandons de bien vouloir informer l'investigateur de votre décision.

Toute information personnelle vous concernant obtenue au cours de cette étude sera traitée de manière confidentielle ; les données enregistrées au cours de l'étude vous concernant seront identifiées par un numéro de code et vos initiales.

Le fichier informatique utilisé pour réaliser la présente recherche a fait l'objet d'une autorisation de la CNIL en application des articles 40-1 et suivants de la Loi " Informatique & Libertés ". Les données médicales vous concernant, ainsi que celles relatives à vos habitudes de vie compte-tenu des nécessités de la recherche (s'il y a lieu), font l'objet d'un traitement informatique et ne seront transmises qu'au promoteur ainsi que, le cas échéant, aux autorités sanitaires habilitées dans les conditions garantissant leur confidentialité. Vous pouvez exercer vos droits d'accès et de rectification auprès du Dr_____ .

En cas d'effet indésirable survenant en cours d'étude, vous devrez en informer immédiatement l'investigateur.

Vous recevrez un exemplaire de ce document, un exemplaire (l'original) sera conservé par l'investigateur, et un autre exemplaire sera mis sous enveloppe scellée inviolable par l'investigateur, qui la transmettra au promoteur, conformément aux recommandations françaises. Cette enveloppe ne pourra être ouverte que par l'investigateur ou par les autorités à leur demande.

Vous pourrez obtenir toute information complémentaire en cours d'étude auprès de l'investigateur_____.

J'ai lu le document d'information relatif à cette étude. J'ai reçu une explication sur la nature, l'objectif, la durée, les effets et risques potentiels de l'étude et sur ce qu'il m'est demandé de faire. J'ai reçu toutes les réponses souhaitées à mes questions.

J'ai fait part à l'investigateur de tous mes antécédents médicaux ou maladie actuelle, de tout traitement médical en cours.

Par ailleurs, je l'ai informé de ma participation à toute autre étude clinique au cours des _____ mois précédents.

J'ai bien compris que ma participation à cette étude est entièrement volontaire et que je suis libre de refuser d'y participer, ou de retirer mon consentement à tout moment, sans préjudice pour ma santé.

J'accepte que les données enregistrées à l'occasion de cette étude puissent faire l'objet d'un traitement informatisé par le promoteur ou pour son compte. J'ai bien noté que le droit d'accès prévu par la Loi "Informatique & Libertés" (Article 40) s'exerce à tout moment auprès de l'investigateur. Je pourrai exercer mon droit de rectification auprès de ce même médecin. J'accepte que les résultats de l'étude soient communiqués aux autorités concernées, au promoteur de l'étude. Mon nom et mon adresse seront gardés secrets.

Après en avoir discuté et avoir obtenu une réponse à toutes mes questions, j'accepte librement et volontairement de participer à cette recherche et je donne mon accord pour participer. Ma signature atteste que j'ai clairement compris les renseignements concernant ma participation à ce projet de recherche.

Personne donnant le consentement :
Je confirme avoir reçu un exemplaire du document d'information et de consentement en rapport avec l'étude.

Nom _____ **Prénom** _____
(en lettres capitales) (en lettres capitales)
Signature _____ **Date** _____

L'Investigateur :
Je confirme avoir personnellement expliqué la nature, l'objectif, la durée, ainsi que les effets et risques prévisibles de l'étude à la personne dont le nom figure ci-dessus et qu'il/qu'elle consent à participer à l'étude.

Nom _____ **Prénom** _____
(en lettres capitales) (en lettres capitales)
Signature _____ **Date** _____

Appendix E: Pilot Confirmation Statement

The purpose is here for the pilot to confirm that the participant has received proper information about the pilot to enable him/her to give informed consent.

This part will be filled in by the pilot.
The original will be given to the participant; a copy will be kept by the pilot.

I have given this research participant information on the study, which in my opinion is accurate and sufficient for the participant to understand fully the nature, risks and benefits of the study, and the rights of a research participant. There has been no coercion or undue influence. I have witnessed the signing of this document by the participant.

Investigator's Name: _____

Investigator's Signature: _____

Date: _____

Appendix F: Documentation of Consent

The purpose of this is to record the participant's identity in relation to the informed consent form affirming that informed consent was given.

This part will be filled in by the participant. The original will be kept be the investigator; a copy will be given to the participant.

The information shown below identifying the participant should be entered in the designated spaces at the time of execution of the consent document.

Participant's Name: _____

Participant's Birth Date: _____

Participant's Reference Number: _____