LILY
Advanced Support for Independent Living; Human Life Cycle Approach in Senior Housing

LILY Project (AAL-2010-3-027)

Deliverable D1.1/D1.2

Ethical and Legal State of the Art and User Involvement

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1. Abstract / Executive summary

In a project such as LILY whose success depends on adequate and effective user involvement in order to achieve its goals, there is a variety of ethical issues that need to be taken into account. Whenever users are engaged in a research project, it is of pivotal importance to consider any ethical aspects with regard to recruitment and participation as well as documenting, recording, analyzing, processing, accessing and storing the data collected. To conduct ethically sound research means to show respect for one's research subjects, for their dignity and autonomy, for their self-determination and therefore for their own decisions and standpoints. It also means to do no harm, to minimize the risks and maximize and share the benefits, and to ensure the research subjects' safety and privacy. How these rather general terms can be and already have been translated in practice will be the topic this report.

This deliverable is organized in the following way: Chapter 2 forms a short introduction to the LILY project and the relevance of ethics in the project. In chapter 3 general ethical principles in research will be presented. In chapter 4 an overview of ethical issues emerging in various stages of a project and strategies to deal with these issues will be given. Chapter 5 contains short examples of case studies and project reports with a focus on the ethical guidelines which were developed by the authors. Chapter 6 presents questions to be posed in all stages of a user study in a checklist format and provides one sample confirmation document for informed consent that can be modified by partners for their use. The report concludes with a collection of policies and legal frameworks applicable in the countries where LILY research takes place.

2. Introduction

2.1 About LILY and why ethics

LILY (Advanced Support for Independent Living; Human Life Cycle Approach in Senior Housing) is a cooperative project with the objective to create a sustainable senior-centered system for the comprehensive innovative management of independence and participation in the 'Self-Serve Society' via advanced ICT for people aged around 55 and above.
The target groups of the system are

- older persons living in their private home who can use the system to manage their activities of daily living (ADL).
- care givers, social workers and family members who can use the system to stay in contact with their clients/relatives, jointly arrange activities and receive feedback
- public and private service providers who can announce activities and/or offer various kinds of services.

In the project products and services will be prototyped and validated in two pilot sites (Finland and France). Time to market for the system is expected to be one year.

In a project such as LILY whose success depends on adequate and effective user involvement in order to achieve its goals, there is a variety of ethical issues that need to be taken into account. Whenever users are engaged in a research project, it is of pivotal importance to consider any ethical aspects may emerge with regard to recruitment and participation as well as documenting, recording, analyzing, processing, accessing and storing the data collected. As LILY targets three user groups and thereby addresses a variety of stakeholders, it is necessary to continuously assess the ethical implications the services/applications may have for their interrelations/relationships.

This document as part of the Work Package 1 (Deliverable 1.1/1.2) sets out to answer three interrelated questions:

- What are the ethical issues that can be expected to be surfacing in the course of the LILY project?
- How have these or similar issues been dealt with in the literature/in other projects so far?
- Which policies/good practices can be developed from this
    - in the recruitment of users?
    - in the involvement of users in the project's activities?
    - dealing with users' data (collection, storage for the purpose of the project, analysis, dissemination)?

The good practices to be developed will be grounded in the four key ethical: non-maleficence, beneficence, justice and autonomy (Bowes et al., 2012: 8). A deep understanding of emerging ethical issues is necessary to be able to develop an ethical policy which will serve as guidance for the LILY project from its outset on. Throughout the project the ethical policy needs to be closely monitored and revised, should new aspects emerge which the policy had not been included.

2.2 Literature reviewed

The first part of the literature used in this report was found via *Springer Link Database* and *Web of Knowledge* (search strings: Ambient Assisted Living AND ethic* and sensor AND ethic*) and the journals *Universal Access in the Information Society*, *Information Culture, Society* and *Technology and Disability* and the bibliographies and related works outlined in the papers found.

Further on in the process a second literature research was conducted using the databases *PubMED* and *Web of Knowledge* (search strings: telecare AND ethic*, telehealth AND ethic*, AAL AND ethic*, Ambient Assisted Living AND ethic*, ICT AND ethic*, assistive AND ethic*). Non-original research articles such as review papers and metaanalyses were excluded from the second results, as were papers in languages other than English or German and database entries without abstracts.

2.3 Structure of the document

This report is organized in the following way: In chapter 3 general ethical principles in research will be presented. In chapter 4 an overview of ethical issues emerging in all stages of a project and strategies to deal with these issues will be given Chapter 5 contains short examples of case studies and project reports with a focus on the ethical guidelines which were developed by the authors Chapter 6 presents questions to be posed in all stages of a user study in a checklist format. The report concludes with a collection of policies and legal frameworks applicable in the countries where LILY research takes place.

3. Ethical Principles in Research

This report will focus exclusively on ethical issues in RTD. Ethical issues to be considered in the phases of deployment, distribution and use of the products and services developed in the field of Ambient Assisted Living lie beyond of the scope of this report. Up to this date, no explicit ethical guidelines or a code of ethics exist for the field of AAL. Rauhala/Topo give some explanation for this lack of ethical codes of conduct: "The fact that codes of conduct tend to be profession-specific may to some extent explain why no widely accepted guidelines have been adopted to regulate technological research and development work in the field of assistive technology for frail older persons, which is often done by interdisciplinary project teams." (Rauhala/Topo, 2003: 208) In the medical field, as is widely known, the situation is very different and professional codes of conduct are an important prerequisite for research with human subjects. While the danger of side effects in drug testing have led to strict guidelines regarding the safety of the participants and there furthermore has been a general trend to rather restrict participant involvement in clinical trials, the situation in the development of assistive technologies is different: "[T]he disability movement and authorities recommend user involvement in the development of assistive technologies." (ibid.: 209)

In the core section of their paper Rauhala/Topo identify eight parallels between clinical and enabling technology research:

- Trial participation does not equal benefit
- Informed consent
- Participants can incur costs
- Situation after trial
- User groups with special needs
- Raising unfounded expectations
- Ethics committees

Even if there are substantial differences between user involvement in clinical and enabling technology trials, these parallels encourage researchers to consult seminal documents from the medical field in order to lay the foundations for ethically sound research.

In 1979, the United States' National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research published the Belmont Report to identify and summarize "basic ethical principles that should underlie the conduct of biomedical and behavioral research involving human subjects and to develop guidelines which should be followed to assure that such research is conducted in accordance with those principles."[1]

Following the Belmont Report, the basic principles in research involving human subjects are:

- Respect for persons ("the requirement to acknowledge autonomy and the requirement to protect those with diminished autonomy.")

[1] The Belmont Report is available at: http://www.hhs.gov/ohrp/humansubjects/guidance/belmont.html

- Beneficence ("Persons are treated in an ethical manner not only by respecting their decisions and protecting them from harm, but also by making efforts to secure their well-being.")
- Do no harm
- Maximize possible benefits and minimize possible harm
- Justice ("Who ought to receive the benefits of research and bear its burdens? (…) For example, the selection of research subjects needs to be scrutinized in order to determine whether some classes (…) are being systematically selected simply because of their easy availability, their compromised position, or their manipulability, rather than for reasons directly related to the problem being studied.")

Also in other research contexts than medicine, the field the Belmont Report was originally produced for, these basic ethical principles apply. The "Ethical Principles of Research in the Humanities and Social and Behavioural Sciences" for instance, produced by the Finnish National Advisory Board on Research Ethics[2], set forth the following strategies for conducting ethically sound research, which are in accordance with the Belmont Report and are based on the same basic principles.

- Respect the autonomy of research subjects. (Obtain informed consent, which needs to be voluntary and free, through a procedure which ensures that the research subjects comprehend what they are signing up for.)
- Avoid mental, physical and social harm. (Assess risks, ensure safety and avoid harm in recruitment, participation and after the project has ended.)
- Protect personal data and confidentiality in research and publication. (Establish a sound privacy policy and protect the research subjects' personal data.)

The very thorough and highly useful Ethical Issues Compilation Report produced in the project *ICT & Ageing: Users, Markets and Technologies* documents and analyzes ethical issues which arise in research and deployment of technology in the field of ICT and aging. According to the authors it is viable to adapt the ethical guidelines depending on what kind of data gathering methods will be used in a specific project. If, for instance, the data collection in a user requirement study includes methods such as interviews or participant observation, the adherence to social scientific codes of conduct and of informed consent should suffice. If, on the other hand, a pilot study is planned in a lab or if participants receive prototypes to try out in their homes, clinical codes of conduct for research should be consulted. (cf. Kubitschke et al., 2009: 39).

So what can be taken away from these documents so far, what does it mean to conduct ethically sound research? It means to show respect for one's research subjects, for their dignity and autonomy, for their self-determination and therefore for their own decisions and standpoints. It also means to do no harm, to minimize the risks and maximize and share the benefits, and to ensure the research subjects' safety and privacy. How these rather general terms can be and already have been translated in practice will be the topic of the upcoming chapters.

[2] Available at: http://www.tenk.fi/en/index.html

4. Ethical issues in research

Some general - albeit hardly surprising - trends can be identified in the literature on ethical issues in research and development of ICT-based technology for elderly persons. If the user group has a heightened vulnerability, ethical issues in research and development of assistive technology for dementia patients and/or their carers are widely discussed (e.g. Mahoney et al., 2007; Niemeijer et al., 2010; Landau/Werner, 2012). Also, the more medical-related the envisioned products or services are, the more can be found on ethical conduct in research (such as ICT in the field of telehealth), even if these seem to be restricted to a few common issues while others are left aside.

This is illustrated in Marziali et al. who reviewed practice standards and research ethics in technology-based health services and interventions for elderly people. Their starting point was that "most of the disseminated research on the ethical and legal aspects of telehealth has focused on the risks associated with protecting patient privacy and confidentiality and on issues related to informed consent" (Marziali et al., 2005: 682-83) while other equally important ethical dimensions such as the minimization of risk are not at the forefront. Through a systematic review they show that the main ethical issues reported in the studies was"[i]nformed consent (50%), a mechanism for monitoring participants (38%), confidentiality and protection of privacy (27%), REB or IRB approval (22%), and a mechanism for contacting the health provider (22%) (ibid.: 686) and that the number of ethical issues reported was generally rather low: "almost half (48%) of the sample reported fewer than 3 ethical issues." (ibid.) They also found that references to ethical issues relevant in research for and with elderly people – such as constraints in the ability to give informed consent or a heightened vulnerability of elderly participants – were often missing (ibid.: 692).

In this chapter, ethical issues, which are considered to likely arise in different phases of a research project, and strategies, which have been applied before and have been found valuable, will be presented. To conduct a study in an ethically sound way does not only mean to have well thought-through consent forms and information letters, to generally treat research subjects with respect, and to keep them safe from physical, mental and social harm. Ethically sound research includes approaching a study in an ethical way before it has actually started and letting it fade out in an ethical way after it has been finished. What exactly this means will be explained on the following pages of this report.

4.1 Research with vulnerable user groups

The website Social Science Research Ethics at the University of Lancaster[3] is a valuable resource on ethical issues and guidance in research in general, but especially for every individual considering or conducting research with potentially vulnerable groups. The general principles of respect for individuals' autonomy, dignity and self-determination, of beneficence, non-malfeasance and justice of course apply to all research subjects. Yet, special attention needs to be paid if one is doing research with vulnerable groups of people. The authors contributing to the website state that to speak of vulnerability means "to refer to those individuals or groups who, due to age, ill-health, infirmity, minority status or their otherwise disempowered position in society may be open to

[3] Available at http://www.lancs.ac.uk/researchethics/4-1-intro.html

exploitation (whether physical, emotional or psychological)." (Truman et al., n.d.) Their vulnerability must not be exploited for one's own research-related benefits and research must under no circumstances enhance a research subjects' vulnerable position. The vulnerability issue extends to all stages of research, from recruitment and data gathering to dissemination and publication of the results.

Especially in research with a vulnerable group of participants, the recruitment process and the informed consent procedure can bear some ethical pitfalls. It needs to be ensured that the participants in the study do not feel forced to participate or "feel they have no choice or that refusing the new service will have adverse consequences on their situation." (Kubitschke et al., 2009: 29) There may be different interests for participation involved and therefore conflicts of interest may arise if members of the secondary or tertiary user group want (them) to participate and the person being cared for does not, is undecided or reluctant. Care relationships and relationships between doctors or other medical personnel or service providers and elderly people are not power- and hierarchy-free relationships. Therefore it is necessary to consider if the recruitment process, the research situation and/or the product itself lessens or heightens a potential hierarchy. Due to an axis of dependency on a person caring for the participant, consent for participation might be given even if the participant him- or herself does not want (or does not care) to participate but is convinced by the carer. This is also pointed out in the ICT & Ageing report: "It should be very clear to older people who are asked to join in a research project that their not wanting to participate will not affect their service provision." (Kubitschke et al., 2009: 40).

In order to avoid any misunderstandings here and to keep care and research apart, it may be useful for carers or personal physicians not to be involved in the recruitment process (cf. Aronson, 2002: 402), or, put differently, that unequal relationships in recruitment are avoided by all means. Also, if the research takes place in the context of an institution, researchers need to be aware of subtle hierarchies and power relationships at work. "[T]he researcher may not necessarily be aware of the pressures to which potential participants are subject (…). In institutional settings, where conformity and compliance are rewarded, people may not feel that they have a *real* choice. Older people in care homes may feel disempowered and give consent as a matter of habit." (Truman et al., n.d.) It is of utmost importance that the participants in such research contexts know and are being reminded throughout the study that their participation is voluntary and not in any sense obligatory or necessary for their care. Mahoney et al. raise an interesting issue regarding research in care facilities and the possibility of staff acting as research partners, co-investigators or interviewers. They state that if staff takes such a role, they "would need certification in human-subject research. Alternatively, if staff members serve as subjects to be interviewed or to test a technology, they need to participate in the consent process, with the clear specification that they can refuse to participate without any negative reprisals in the workplace." (Mahoney et al., 2007: 223).

In order not to harm the participants and to avoid mental risk (see chapter 3.3.2), the methods for data gathering must be appropriate for the capabilities of the research subjects. Dickinson et al. point out that "frail older people are more vulnerable to the negative effects of unsuitable technology as well as to potential discomfort in taking part in certain forms of requirement gathering exercise" (Dickinson et al., 2003: 1). Possibly distressing topics need to be approached in a sensitive way, allowing the participants to decline to answer any questions they do not wish to answer and to have in place procedures to cushion troubled emotions. Apart from the general requirements to protect the research participants' privacy by all means and to end the study in a way so that research participants do not feel exploited (see chapter 3.4), it also needs to be ensured that they face no negative consequences through their participation on an individual, but also on a collective level. Research must not contribute to the reinforcement of stereotypes – particularly

negative ones (cf. Truman et al., n.d.). Therefore, researchers are required to critically question their own assumptions regarding the group they study, how these assumptions may find their way into the study design, the methods applied and the interpretations of the findings.

4.2 Pre-study

4.2.1 Ethical clearance

In some countries, research involving human subjects may require formal ethical clearance. Therefore, prior to any recruitment, the researchers have to inquire if they need to obtain any formal ethical clearance in the countries where the research is being conducted, which ethics committees are in charge and how the clearance process is structured. If ethical clearance is needed, no recruitment of participants and no research involving persons shall take place before it is obtained.

4.2.2 Informed consent

Valid consent comprises three elements: consent needs to be competent, which means that the person giving consent has "the capacity to make the relevant decision" (Ganyo et al., 2012: 1356), it needs to be informed, as the person giving consent has been appropriately instructed and knows what their giving consent entails, and it needs to be free and voluntary and therefore given without any form of coercion (see chapter 3.1).

The consent procedure needs to be structured in such a way that true voluntary, informed and competent consent can be given, adapted to the participant's capabilities. As participants cannot be expected to have expert knowledge regarding technical issues, the language should be kept as easily understandable and non-technical as possible, without leaving out relevant information which the participants will need in order to give informed consent. This may need some greater reflection on the side of the researchers preparing the informed consent document as Picking et al. point out: "The use of any jargon should be avoided, but in today's hi-tech world, that is not as straightforward as it may seem. Words such as 'internet' and even 'computer' are still not universally used household terms, especially when elderly people are concerned (…)" (Picking et al., 2012: 109) It might be possible that the informed consent document may need to be adapted and its language simplified even more.

Most of the time, informed consent will be given in written form after the participants have read or have been read to an information letter with all relevant details regarding the aim, methods and scope of the study. Yet, in some cases and with some user groups it might be useful to approach the informed consent process in a way that includes different media. In the Friendly Rest Room project for instance, the researchers operated with a broad and extensive informed consent process. "Different media were used to convey information about the project, the depth of the information increased with time. (…) Users were provided detailed information regarding expectations on time to be spent, a schedule of events, descriptions of tasks, and the setting itself. In an informed consent form, the main information was summarized, and the usual rights of the participants were repeated." (Rauhala, 2011: 54).

Choosing such a strategy can be of great value as after some time users may forget what exactly it was that they gave their consent to and adding different media to the process might serve as a

countermeasure. Klein/Schartz investigated ways to improve participants' long term memory and therefore their understanding of what they gave their consent to. In their empirical yet exploratory study, they used the same informed consent document but presented it to their participants in three different ways: first, the control condition with a paper-based informed consent form which additionally was verbally explained to the research participants, second, the multimedia condition, where the informed consent document was explained to participants via a screen and loudspeakers without requiring their interactive participation, and third the interactive multimedia condition. In this third setting, the participants steered the presentation of the informed consent document via clicking a button, being able to jump back and also to replay the narration (cf. Klein/Schartz, 2012: 9). All three groups of participants were subsequently tested regarding their knowledge on the content. The results point in an interesting direction, underlining claims for an informed consent process which includes other material than just pen and paper: Even though an interactive and multimedia-based approach to informed consent is more time-consuming, the understanding and therefore the ability to give truly informed consent was enhanced significantly.

Consent needs to be valid in all stages of a project, especially if users participate over a longer period of time. In their article on ethical issues in the use of fall detectors, Ganyo et al. argue for a continuous approach to consent. They give the example of an elderly woman with mild dementia who originally consented to having video cameras installed in her apartment and was understood to have been fully informed and to have the capacity to consent. "If, at the time of giving consent, she is not able to imagine all the situations that might be observed, does she have the capacity to consent? Even if the user gives valid consent (…), the principle of autonomy would require service providers or carers to respect any change of mind or decision to interrupt the monitoring." (Ganyo et al., 2012: 1357) In the project Friendly Rest Room the researchers worked with a consent procedure in which consent had to be confirmed throughout the research in writing as well as verbally and therefore was renewed for different cycles and during testing (cf. Rauhala, 2011: 55).

To work with a procedure of continuous consent means that consent needs to be given for different stages of the data gathering process as well as if one stage of data gathering continues over a longer period of time. Magnusson/Hanson state, that participants who take part in a longer study (for instance those who have a prototype in their home for a few months) need to be asked for informed consent more than once at the beginning of the project: "families were asked at every stage of the research and development process whether they would like to continue to take part and their right to withdraw were emphasized." (Magnusson/Hanson, 2003: 435) It has to be noted though, that the longer a project runs and the longer participants take part and become acquainted with the research team, the more difficult it becomes for them to withdraw. This needs to be kept in mind, the ethical policy regarding continuous informed consent needs to take this dimension into account. (ibid.), and researchers need to develop a sensitivity regarding more subtle expressions of withdrawal.

Mahoney et al. urge researchers (especially in RTD for Alzheimer's or dementia patients) to "truthfully describe capabilities (or potential capabilities) of residential monitoring technology […] [including] the cautionary tale of limitations along with positive results, emphasizing safety concerns and other social burdens that often ride on the heels of small or large indications of scientific progress." (Mahoney et al., 2007: 221). Even if the research enhances knowledge on a specific topic, enables researchers to better understand the needs of their participants and to further develop the prototypes or systems they have tested, it needs to be ensured that no unfounded expectations will be raised on the side of the study participants. They need to be informed, that they might not be the ones to profit directly from the research they have participated in (Rauhala/Topo, 2003: 209), that they will not be able to keep whichever device or prototype they will receive and that there might not be a product available for them to obtain for quite some time (see chapter 3.4).

The ethical thing to do, therefore, is to be honest and realistic regarding promises, capabilities and limitations of the technology in question and include statements on this matter into the informed consent procedure, thereby directly linking the entry into the research with the phase of exit.

4.3 During the study

4.3.1 Research in people's homes

The home is the place in our lives which is commonly regarded – at least in a culturally and historically contingent Western reading – as a private space, a place of withdrawal from public life, secluded, secure and open only to selected people. Researchers conducting research in homes need to be aware that their research, as does homecare (cf. Aronson, 2002: 402), turns the privacy of home less private but more public which might be a burden to the participants. Due to homes' private nature, research in homes requires researchers to be especially sensitive to issues of privacy and actively take precautions to protect their participants' dignity. They need not only show respect for their participants' informational, decisional and physical privacy (see chapter 3.3.4) but also for the (work) routines and privacy of other people present in the research setting, such as (informal) carers. Mahoney et al. call for research in homes to be as least intrusive and disruptive as possible (Mahoney et al., 2007: 220) while research or systems which include the monitoring of subjects in their homes need to take specific precautions regarding the securing of privacy and confidentiality due to their capability to record "such 'private' functions as using the bathroom, acts of sexual intimacy, or other activities never intended for others to see." (ibid.)

The space and interior of people's homes are organized in a specific and individual way with meaning attached to artifacts and arrangements. Furthermore, the homes of elderly people can can be cluttered and far from the ideal home envisioned in utopian Smart Home design contexts (Axelrod et al., 2009). They can be rather old and lacking (for instance electronic) infrastructure that more modern houses has available. The elderly people might have been living there for quite some time and are used to a specific order and organization of their homes (Kubitschke et al., 2009: 36). Research which relies on a specific infrastructure therefore might disrupt the order or change it considerably. It is not only the order of material things which might be changed through research in homes: Also and especially through a study with a longer duration, the relationships and the often fragile arrangements people employ to live their life in a specific way, might be disturbed.

Still, the home is the place where researchers are able to find out how individuals actually use technology, what it is that they need for their everyday routines, what their activities of daily living look like, how they are organized and how they could be best supported. Dickinson et al. make a case for research in the homes of their study participant vis-a-vis other requirements-gathering methods such as focus groups or questionnaires, methods which can be challenging to frail or impaired elderly people. In-home research, they state, takes place in the participants' normal, familiar and safe surroundings and can contribute to the participants' confidence for instance through the fact that "being in someone's home as a guest increases the host's authority and may contribute to their confidence in discussing the research question." (Dickinson et al., 2003: 3) This role of a guest requires the researcher to be sensitive to the expectations of his or her host: "The ritual of hospitality is often integral to a sense of self, particularly if the host is usually powerless or isolated. Apparently insignificant actions like refusing a cup of tea can make a tremendous difference to the comfort of your host." (Dickinson et al., 2003: 4) The benefits of this specific dynamic of the researcher-researched relationship is echoed in Jokinen et al.: "At home, the informants were obviously on 'home turf' and it was easier for them to feel that they were an

authority on the research topics, while for them the researcher was just someone who wanted to learn about their life." (Jokinen et al., 2002: 167)

4.3.2 Harm, risk and safety

One of the central ethical principles in conducting research is that the research subjects must not be harmed through their participation in the study. Harm can refer to physical and mental harm, but also to social harm. The safety of participants in a study and individuals using the technology or service needs to have the highest priority. Researchers are required to achieve "a balance between avoiding harm and respecting decisions, dignity, integrity and preferences" (Kubitschke et al., 2009: 13) while respecting the trade-offs between risk and security that individuals make. Well-being is a very subjective concept and the ethical principle of autonomy, applying in research and deployment contexts alike, also includes that the trial participants and users have the right to decide by themselves which risks they take, given the fact that they have been put in the position to be able to make an informed decision (cf. in the context of dementia and GPS tracking: Landau/Werner, 2012: 362).

Some authors point to the danger of a decrease in watchfulness on the side of the persons being cared for as well as of the carers (e.g. Niemeijer et al, 2010: 1134; Bowes et al., 2012: 10). Mahoney et al. make a similar point with regard to an increased risk through the presence of researchers as "medical compliance by the caregiver might decline as a consequence of the presence of professional researchers." (Mahoney et al., 2007: 219) Also, the participants in studies which involve communication technology providing "the family and the physician electronic data about the elder's activities" (ibid.: 221) have to be informed and/or reminded that they need to keep up their regular visits to their doctors. The safety risk would be here that the elders might assume that "they are in good hands, and that they and their caregivers can reduce their normal vigilance" (ibid.). In studies with the aim to increase elderly people's use of ICT and especially the internet, not informing participants about the risks of scamming and phishing would be unethical and dangerous (ibid.; Kubitschke et al., 2009: 40).

Another level of risk relates to the change of behavior of the carers in sensor-enhanced settings and the level of reliance on the functioning of the prototype. If a prototype is tested outside the laboratory situation and the study is a "proof of concept" (Mahoney et al., 2007: 221) study, the failure of the prototypes (or of some of their parts) need to be taken into account even if the technology is to be made "as robust and reliable as possible" (ibid.: 223) and the participants must be made aware of this. If for instance one of the sensors fails and there has been a change in behavior on the side of the carers as they rely on the sensors and do not further check on the users as often as they used to, the users are at great risk (ibid.).

In order to avoid mental harm beyond the general principles of respecting the participants' privacy and dignity throughout the study and in publication, researchers and project workers need to pay special attention to more (or less) subtle demonstrations of unease, anxiety and/or exhaustion that participants might display and act accordingly (cf. National Advisory Board on Research Ethics in Finland). Even if participants do not clearly voice discomfort or the wish to stop (this might happen for a variety of reasons such as an inherent power relationship between researcher and researched (Truman, n.d.)), they may well send nonverbal signs which can be recognized by attentive researchers who put the well-being of their research participants first. To avoid social harm, a privacy policy needs to be in place and be adhered to and the privacy and personal data of the participants need to be protected. To do no harm also means to ensure that the participation in a

study or testing a prototype for a longer period of time does not diminish people's capabilities for instance to care for themselves if they still are able to do so and be a substitute for tasks they still can do on their own. Research needs to be done in a way that participants are not reduced to being *sick*, *disabled* or, put differently, for them to get assigned the sick role from the beginning on, but to "approach potential subjects and their families with reassurances that [the researchers] recognize areas of strength and health in the person." (Mahoney, 2007: 220) The participants' self-esteem should be heightened and must not be compromised through participation in research.

On a more abstract level, risk also relates to social relationships which might be affected or even changed through the participation in the study, which is especially important to keep in mind in the context of (informal) care. "(T)he extent to which social and affective relations are shaped or changed in each case will depend on who the users are, what possibilities the technology in question bring and the way in which all these elements interact." (Bowes et al., 2012: 10) Mahoney et al. add to this with regard to monitoring technologies for individuals affected by dementia, but it is an important insight also in the context of care for elderly individuals in general. They state that researchers need to take especially good care of not to negatively influence "workable, healthful arrangements or destroying fragile ones." (Mahoney et al., 2007: 220) This is echoed in the ICT & Ageing study: "[F]amily care arrangements and relationships can often be very precarious and finely balanced, and […] any intervention poses the risk of disruption or even irreparable damage." (Kubitschke et al., 2009: 37) What is needed from the side of the researchers is a great sensitivity for social relationships, and how not only the system which is introduced into the home of an elderly person in the trial, but also the mere presence and the attention of researchers affects these close and immensely important relationships. Care is not a one-way road, where one person takes the active part and cares for another person who takes the passive part. As Bowes et al. phrase it, "the processes of care are processes of co-production" (ibid.: 14) and care is coming to be seen more and more as a partnership endeavor (ibid.: 14), a partnership which might change during the course of a monitoring project or trial.

This is a dimension of risk which has not been studied in detail, and one reason for this might be that most of the research emanates from pilot projects (cf. Marziali et al., 2005 in the context of telemedicine). Most of the products or services which are developed are in prototype stage and after the project stops the prototypes are no longer tested, so longitudinal studies or even long-term experiences are not yet available. The same holds true for telemedicine technologies, where risk also needs to be understood in a medical way. Marziali et al., writing from a rather positivist standpoint, add to this by stating "[d]espite the positive results of pilot studies that show benefits of telehealth services delivered to older adults in their homes, there are few randomized controlled trials comparing telehealth interventions with conventional care practices" (Marziali et al., 2005: 693) While through the consent procedure participants need to be explained the risks of their participation, in the context of lifestyle monitoring or any other highly innovative field of RTD it might be difficult to inform the participants about the risks as there is little evidence available regarding what the risks of participation actually entail. (Bowes et al., 2012: 18)

4.3.3 Transparency, control and purposefulness

Zagler et al. present their lessons learned from a user study they conducted and emphasize that it is of utmost importance to offer full transparency regarding what a system can and cannot do (Zagler et al.: 4) It should be well explained to participants how the services or devices work and what data will be collected (cf. Kubitschke et al., 2009: v) and used in which way. Individuals have the right to decide which of their data is being collected, processed and stored. In order to be able to make a

decision on this matter, they must be well informed regarding the scope of the study and the nature of the data being collected. Participants therefore need to understand in detail what the study will aim for and what will be done in the trial, what kinds of data will be collected, processed, analyzed and stored. As stated above, this needs to be done in a way so that users or participants understand it well – overtly technical language or jargon should be avoided.

With regard to transparency, it is necessary to carefully weigh the risks and benefits of what is too much and what too little information about the workings of the system or the prototype. Information and feedback is extremely important, especially "[w]hen things happen effortlessly, e.g. simply by being close to [a] tag" (Kosta et al., 2010: 307) Participants need to be able to tell when the system is working, if and if not information is recorded and/or transferred someplace else. While devices are expected to work non-obtrusively and non-disruptive for a number of reasons, one of them being to avoid stigmatization (Kubitschke et al., 2009: 28), this movement into the background can further obscure the workings of the device/the technology. Hensel et al. point to the importance to recognize "the link between obtrusiveness and acceptability". They identify a dominant ideal of unobtrusiveness with the consequence that ideally technology moves so far into the background, that it is easy for people to forget that they are being monitored. This could lead in essence to the (in most cases unethical and therefore unacceptable) situation of a "covert" observation (Hensel et al., 2006: 14). Zagler et al. call for "a good balance between unobtrusive and completely hidden technology" as "a completely hidden system, where the user cannot see anything of the components and their functioning could become eerie and threatening." (Zagler et al., 2008: 4) Bowes et al. add that through lifestyle monitoring technologies there is a threat to a central ethical dimension, namely autonomy, in the sense that "some decisions about if or when to call in health or care professionals may be taken out of the hands of the individual" (Bowes et al. 2012: 14) but also in the sense that autonomy may decrease as the user's dependency on the system increases.

Even if a good balance between unobtrusiveness and disappearance has been found, as a general principle the users should have the right to self-determinedly switch off the system or overrule it. Yet the question is in how far this is inscribed in the technology and how much control is given to which user(s), a question which needs to be reflected on in great detail beforehand. Working in the context of Alzheimer's and dementia, Mahoney et al. state that it is important to consider "any leeway the subjects or surrogates are allowed in controlling the technology, such as who determines when the technology will be used, or whether it will be continuously on, or if the control to shut it off is given to caregivers" (Mahoney et al., 2007: 223)

Following the principle of purposefulness (Kubitschke et al., 2009: 30), researchers should collect only the data which is needed. It is very tempting, to gather lots of data, just because it is technologically possible, yet this is not ethically appropriate. This also exceeds to the technology and devices used in a study. The authors of the ICT & Ageing-study call for proportionality regarding the technology involved, stating that "functionalities and equipment should be selected because they are really needed, not because they are available, fashionable, interesting to work with and so on." (Kubitschke et al., 2009: v)

4.3.4 Privacy issues

Via lifestyle monitoring an immense amount of data can be collected, data ranging from all kinds of bodily signals to mobility patterns and activities of daily living. As Bowes et al. put it: "The intimacy and detail of the data that lifestyle monitoring can collect is one of its central attractions." (Bowes et al., 2012: 17). Magnusson/Hanson point out that through computers' capabilities to store ever growing amounts of data new ethical problems arise (ibid.: 436). As such great amounts of

data can be collected at great ease, new rules for privacy need to be developed alongside with the technology itself. "[W]hat rules of privacy should apply in relation to adherence to medication / treatment regimes, health-promoting or health-threatening dietary or other habits (…) and who should have access to such information." (Kubitschke et al., 2009: vi) In order to protect the privacy of the individuals it was collected from, it is necessary to put down rules and regulations of how the data will be processed and stored and who will have access. Bowes et al. assured their participants the anonymization of the data and a de-individualization through a presentation as group data, which makes it impossible for anyone outside the research team to assign data to individuals (ibid.: 436).

Ikonen/Kaasinen make a very interesting and highly relevant point in this context.. According to them privacy is often mainly understood and addressed as information (or data) privacy. Yet, "AmI solutions bring in the needs for spatial and bodily privacy as well." (Ikonen/Kaasinen, 2008: 4) Bharucha et al. add to this and state that the legal concept of privacy includes three categories: physical privacy, informational privacy and decisional privacy (Bharucha et al., 2006: 614). Following Hensel et al., physical privacy refers to the notion of personal bodily space: "Physical privacy is related to both the degree to which one is physically accessible to others and the accessibility of one's personal space or territory and may be violated when telehealth technology impinges on the user's control of such access." (Hensel et al., 2006: 429) Decisional privacy is "principally concerned with choice, an individual's ability to make certain significant decisions without interference" (Kang, 1998: 1202) and thereby deeply rooted in the ethical principle of autonomy. If an understanding of privacy does not include these other highly relevant dimensions of privacy, truly ethical conduct in research, design and deployment is hardly possible.

Especially in monitoring research settings, concerns about privacy and "being viewed or seen" are high (Bowes et al.: 12), even though in the project Bowes et al. speak about there were no cameras involved and movement profiles were established via infrared sensors. Still, there seemed to have been great anxieties among the research participants concerning their privacy, which caused a number of individuals to withdraw from the study. The installment of sensors or other means for monitoring behavior always moves along the fine line of enabling security and exerting control, while transgressing boundaries (such as public and private) which normally are rather fixed and sealed off (Bowes et al.: 12). If these are transgressed and surveillance technology is installed in the home, new boundaries emerge, as there appear more or less accepted areas of surveillance technologies in the home, areas which seem to be more or less problematized, more or less ethically challenging, more or less private but always associated with socio-cultural norms (ibid.: 13).

Truman et al state that the right to privacy translates into two imperatives: anonymity and confidentiality. In order to protect the participants' anonymity it to be ensured that none of the data collected can be retraced to the participants it was gathered from. The participants' real names as well as the names of places or institutions must not be used (unless it has been in writing agreed upon otherwise), but they should be assigned unique identifiers (pseudonyms or codes) from the earliest stage on in order to avoid publication mishaps. Should any photos be used on which the participants might be identified, they always have to be asked in advanced and must give their consent to publication – otherwise the photos must not be used. Confidentiality of data implies that data needs to be stored securely, for instance in locked cabinets (audiovisual material, hard copies) or on secure servers (electronic data) and be kept only as long as the data is needed for the purpose it was gathered (cf. Truman et al., n.d.). Only authorized persons may access the data and to facilitate this, a list of authorized persons should be kept and also made available to the project coordinator. It might also be useful to keep access logs in order to be able to reconstruct who has been accessing the data and when.

4.4 Post-study: post project management

Attention to be paid to ethical conduct does not end with the formal conclusion of the study. Post-project management refers to strategies dealing with dependencies which the participants in the study might have developed and more generally to ending participants' involvement in the project in an appropriate, respectful and ethically sound way. The post project-situation of the participants already has to be taken into account before the testing has started. Researchers may face a dilemma here, as Fitzpatrick et al. point out: "If we want to leave the technology with the patient after the prototype study has been completed, there is then the matter of how the maintenance and repair of early prototypes are managed in the absence of continuing resources. On the other hand taking the technology away, having left it with the patient for three months and having said it may help, is also very difficult to do." (Fitzpatrick et al., 2010: 52).

The ethical thing to do would be to at least inform the participants upfront that the prototype they will receive will not remain with them after the project has ended and to address this already in the informed consent procedure. This is something that also Mahoney et al. call for in their ethical guidelines: "Ensure that the elders and families are aware from the beginning if the technology will or will not be available for continued use upon study termination. If not, prior to concluding, share information about other relevant resources." (Mahoney et al., 2007: 224) – otherwise there is the danger of putting participants at risk. While Magnusson/Hanson (2003) for instance show, that during the project the participants' independence was enhanced through the prototype, new forms of dependencies arose as "families in several partner countries [became] dependent on the ACTION services." (ibid.: 435) In ACTION, two municipalities implemented ACTION as part of their care services. (ibid.) This example makes it obvious that it is necessary to come up with some kind of end-of-trial option for the people who have developed dependencies and to whom withdrawal would pose at risk.

While the researchers benefit from the conclusion of the project for instance through possibilities for publication, the benefits for participants are reduced once the project is over and, as Fitzpatrick et al. experienced, participants may "[express] a frustration about helping out with research and then not hearing about outcomes after their involvement is finished." (Fitzpatrick et al., 2010: 52) Furthermore, participants might have gotten used to the attention and to the excitement, their social status might have risen through their participation in a scientific endeavor, through interesting and maybe even exotic technological devices which they had at their disposal, or they might have gotten used to or grown fond of the technology they tested. Rauhala/Topo point out that "[T]he subjective meaning of (…) a technology for a person who has become used to and dependent on it during the trial can be significant for the well-being of that person." (Rauhala/Topo, 2003: 210). After the project is over, the attention suddenly stops and the prototypes and with them the symbolic markers are withdrawn. It is necessary to end the participants' project involvement in a way that is appealing and respectful to the participants especially since the Living Lab operations will be in effect for a great amount of time. One way of dealing with this issue could be to come up with a way of informing them about the results and to acknowledge their contribution and importance to the finished study and to end their involvement gradually.

5. Examples of ethical considerations and guidelines in fields related to the LILY project

5.1 Mahoney et al. (2007): In-home monitoring of persons with dementia: Ethical guidelines for technology research and development

This review article on ethical issues and RTD of home monitoring technology establishes an ethical framework for RTD (Mahoney et al., 2007: 219-21). The authors center "humanistic concerns" such as respect for persons with conditions warranting residential monitoring, their family caregivers and family relationships, for individual differences and for the person's healthfulness. "Research needs and concerns" are on the next level of their framework, requiring proportionality as well as privacy and confidentiality protocols in order to be ethically sound. Researchers also have societal obligations – these are found on the uppermost level "Technology: promises and concerns in societal context" and include justice and distributional fairness as well as trustfulness, prudence, and humility as virtues. The ethical guidelines they developed are based on these principles and give hands-on ethical guidance for researchers in the field and reviewers alike and support ethically sound research in all stages of a study They are structured along the following dimensions:

- Respect (e.g. „For family caregivers and fragile family relationships by minimizing the intrusiveness and performance demands of the technology & study protocol.")
- Autonomy and informed consent (e.g. „Consider cultural differences wherein the head of household or other key decision maker in the culture is involved even if the participant has the capacity to consent.")
- Beneficence (do good) (e.g. „Write technical directions for users in lay language at an elementary reading level.")
- Justice and distributional fairness (e.g. „Provide equity of participation in testing and use of new technologies.")
- Non-Abandonment (e.g. „Ensure that the elders and families are aware from the beginning if the technology will or will not be available for continued use upon study termination. If not, prior to concluding, share information about other relevant resources.")
- Non-malfeasance (do no harm) (e.g „Inform users that technology generated prompts, alerts, or transmissions may not happen when there is a loss of telecommunications /power outages/web access.")
- Privacy and confidentiality (e.g. „Honor the moral dictates of the participants' rights.")

(Mahoney et al., 2007: 224)

5.2 Ikonen/Kaasinen (2008) Ethical Assessment in the Design of Ambient Assisted Living and Kosta et al. (2010): Mobile-Centric Ambient Intelligence in Health-and Homecare – Anticipating Ethical and Legal Challenges

These papers emanate from the MINAmI project and show how emerging ethical issues were dealt with in this project and how they found their way into ethical guidelines. The authors cover ethical issues that emerge during the design of applications and services based on the MINAmI platform as well as those which can be expected to emerge when the platform is implemented (therefore they address ethics of design/research and deployment ethics). In another paper, MINAmI researchers define the need for hands-on ethical guidance as follows: "Ethical principles tend to be easily acceptable but not so easy to concretise and adapt to the design. Our aim is to define ethical guidelines that would be concrete enough to understand and easy to follow by service designers and application developers." (Kosta et al., 2010: 305)

The guidelines[4], which can be understood as a normative framework, are divided into two parts. First of all, every principle is broken down into guidelines for design and issues to be studied in user evaluations (or issues to be discussed in the society respectively). The guidelines for design address the areas of application, platform and service design and give hands-on ethical guidance also in technical terms. Issues to be studied in user evaluations translate these design requirements into empirical questions such as "Do people feel the monitoring of their behaviour acceptable?" or "What kind of reminding people need about of [sic] continuously active systems?" (Ikonen et al., 2008: 5-6). The section 'issues to be discussed in the society' asks serious and tricky questions about the role new technologies can play in society such as: "Should embedding of tags and sensors in the environment be regulated?", "Are people allowed to refuse using new technologies?" or "Can all citizens be provided with equal possibilities to anticipate health hazards?" (Ikonen et al., 2008: 10).

Also the way the project was set up is interesting: They had an Ethical Committee whose task it was to produce and maintain an ethical guidance document for the user evaluation. The document was updated whenever new ethical issues emerged in the course of the project. Apart from the project-based Ethical Committee they had an Ethical Advisory board consisting of external experts who assessed and evaluated the six scenarios illustrating the MINAmI platform (smart pillbox, smart home, sleep plaster, virtual keyboard, memory tag and a hearing device). The Ethical Advisory Board classified their findings into six ethical principles: (Kosta et al., 2010: 319-20), structuring the ethical guidelines which were developed subsequently.

- "*Privacy*: an individual shall be able to control access to hi(s) her personal information and to protect hi(s) her own space."
- "*Autonomy*: an individual has the right to decide how and to what purposes (s)he is using technology."

This includes that the user is in control of the system, can start, stop, configure, overrule it, must receive feedback on the application to be informed whether the system is on or off, whether it is working or not and can also decide if he or she will or will not further use it.

- "*Integrity and dignity*: individuals shall be respected and technical solutions shall not violate their dignity as human beings"

[4] Available at http://www.fp6-minami.org/uploads/media/MINAmI_EthicalGuidelinesforAmI_v12.pdf

- "*Reliability*: Technical solutions shall be sufficiently reliable for the purposes that they are being used for. Technology shall not threat user's physical or mental health."

The principle "integrity and dignity" is in accordance with the Belmont Report's first ethical principle "respect for other persons". Similarly, the way reliability is understood here is in close relation to the medical ethical principle of non-malfeasance, also to be found in the Belmont Report.

- "*E-inclusion*: Services should be accessible to all user groups despite of their physical or mental deficiencies."

While it can be criticized that this principle is formulated in the negative ("deficiencies") the points the authors make and the questions they raise are highly important, such as that the artifact or service needs to be customizable and that no user group is left out without stating good reasons.

- "*Benefit of technology in the society*: The society shall make use of the technology so that it increases the quality of life and does not cause harm to anyone."

In order to achieve this, all different kinds of ways the technology could be used should be thought through. Here the ethical guidance document specifically asks for the development of dark scenarios in platform design. This is especially important and also rewarding in the long run, yet possibly challenging on a funded project-basis.

5.3 Ganyo et al. (2012) Ethical issues in the use of fall detectors

Even if they discuss ethical issues in the context of use of fall detectors (automatic sensors and video monitoring), the checklist they produce to identify ethical issues (cf. Ganyo et al., 2012: 1362) is very useful and could in parts also be adapted to more research-related settings, to guide researchers to ask themselves important questions and to adapt their consent procedures accordingly. Following the principalist approach based on Beauchamp and Childress' framework, they structure the emerging ethical issues along four dimensions:

- Autonomy (e.g. „Does the user have control over the uses of, and responses to, the detector?")
- Privacy (e.g „Do the benefits of using the detectors outweigh the invasions of privacy?")
- Benefit (e.g. „What are the dangers, and possible unwanted effects, of their use both in the short and longer term?")
- Use of resources (e.g. „Have all the people, or institutions, that may be involved agreed to use their resources in the required way?")

(Ganyo et al., 2012: 136).

6. Reminders for User Involvement in LILY – D1.2

In this chapter, comprising the D1.2 User involvement, the main ethical issues that are relevant for bringing users into the LILY context are summarized in a form reminders and check-lists. Drawing on the previous chapters, the ethics of user involvement in the LILY project is laid out for the project's partners to guide their activities with research participants and users. The list of questions provided is meant to assist partners in easily identifying relevant issues that need to be addressed in different phases of user involvement in the project. In order to provide a useful overview, the user participation has been divided into three phases: pre-study, the study itself, and post-study.

The check-list for the study phase highlights especially the need to pay careful attention to the process of informed consent.

The chapter concludes with a checklist and reminder for workshops to be held both at French and Finnish sites and it was circulated to the Coordinator in the beginning of the project.

6.1 Pre-Study

- Is there a requirement to obtain any formal ethical clearance?
- Which ethics committees are in charge of the proposed study?
- How is the clearance process structured?
- How long is the estimated time needed for the formal clearance process?

- Who will be recruited (i.e. how is the group of participants defined) for the study?
- Who is involved in the recruitment process?
- Which possible conflicts of interest can be identified in the field and in the process of recruitment?
- Which possible power hierarchies can be identified in the field?
- How might the research contribute to the heightening or diminishing of the power hierarchies?

- Are the methods used in data gathering appropriate with regard to the capabilities of the research subjects? For example, do the methods to be used support the strengths of the participants?
- Which data is necessary to collect for the project to succeed? Is there a detailed plan regarding what data are to be collected and for what purpose?

6.2 During the Study

- How will continuous informed consent be ensured, over a longer period of time as well as in different stages of the trial and user participation?

- Is the informed consent document written in simple, non-technical language? Has it been sufficiently tested before using it?
- Does it contain all the relevant information regarding the scope and aim of the study as well as regarding the storing, processing and analyzing of data?
- Does it contain information on risks and benefits the participants will experience through their participation in the study?

- Have the participants been reminded that prototypes or some of their parts might fail or not work properly?
- Has it been explained to them what the system or devices can and cannot do?
- Has it been explained to them how the system or devices work and how they will be able to tell how they work?
- Has it been explained to them what data will be collected?
- Has it been explained to them that they might not be the ones to benefit directly from the research and that they will not be able to keep the prototype after the project has ended?

- What kinds of mechanisms are in place to cushion troubled emotions on the side of the participants, in other words, how are possible negative experiences taken into account?

- Have the project workers been instructed to remind participants that they can withdraw from the study at any time?
- Have the project workers been instructed to be attentive to more subtle expressions of unease, anxiety, exhaustion and/or withdrawal?
- Have the project workers been instructed to take good care not to disturb care arrangements or other social relations in the field?

- Are the participants able to tell if the system or device is working?
- Are the participants able to tell if or if not information is recorded and/or transferred someplace else?
- In case of a long-term trial, are the participants able to switch off or overrule the system?

- What measures are in place to secure data privacy?
- How will the data be processed and stored?
- Who will have access to the participants' data?
- Have exit strategies been considered from the point of view of the participants and the researchers?

6.3 Post-study

- What end-of-trial alternatives can be offered to the participants?
- How will the participants be informed of the results of the study?
- How will their contribution be acknowledged?

6.4 Checklist and reminder for workshops

Activity planned: Workshops, focus groups with representatives of intended primary users

Background
Adequate and effective user involvement from the outset of the project is the key to successful achievement of the project's objectives and for obtaining a sustainable and user-centered LILY solution. Whenever users are engaged in a research project it is necessary to consider any ethical aspects that may need to be taken into account with regard to documenting, recording, analyzing, processing, and using the data collected. In what follows, a concise reminder and checklist for partners that intend to involve users and collect data from them within the LILY project is provided, as the consortium is committed to a continuous approach to ethics, in all stages of the project. It is the responsibility of each partner to respect the relevant national ethical guidelines and legal framework that pertains to the work to be performed in LILY. If further ethical issues should be surfacing in the process, please do get in touch with the coordinator.

Need for ethical clearance
Prior to any recruitment, the partners are required to find out whether their planned user activity requires formal ethical clearance. If ethical clearance is required, no recruitment of participants shall take place before it is obtained.

Recruitment
It is necessary to carefully think about who should participate in the study. There can be a variety of reasons for individual participation and understanding these reasons can help in assessing risks, benefits and vulnerability. Compensation for participation is an important issue to consider. It has to be dealt with in a way that does not exploit the research participants but also does not interfere with their voluntary participation in the study. In order to avoid a potential gender bias in the results, make sure to equally recruit and represent male and female participants.

Informed consent
Consent needs to be informed, voluntary and competent. For LILY it is assumed that the participants to be recruited are so-called healthy volunteers. This means that participants can be expected to understand what their giving consent and participation entails. Still, it is the partners' responsibility that the participants are well prepared and informed and can appropriately give their consent. All participants need to receive an information letter and will be given adequate time to read it prior to giving consent and participation. All participants will be asked to sign a consent form. The informed consent procedures will continuously be renewed as the project progresses.

Privacy, confidentiality, anonymity

Data gathering
The partners are reminded to reflect on what data is really needed and to collect only the data necessary for the aims of the project.

Anonymization
It needs to be ensured that none of the data collected will be retraceable to the participants it was gathered from. To achieve this, the partners are urged not to use the participants' real names in any project documentation, but to assign unique identifiers (pseudonyms or codes) to the participants from the earliest stage on (electronic and hard copy). Place names and institutions, which could lead to the identification of individuals or organizations, need to be changed accordingly.

Data storage
All data (audio recordings, video recordings, transcripts, questionnaires a.s.o.) have to be stored in locked cabinets (audiovisual material, hard copies) or on secure servers (electronic data). Lists of unique identifiers must be stored separately from the data they relate to. Electronic data with unique identifiers must be stored on a separate secure server, hard copy data with unique identifiers must be securely stored in locked cabinets. Videotapes, photographs, and other images of participants must also be securely stored in a locked cabinet or on a secure server separate from the participants' data.

Publication issues
In publication, no participant will be referred to by name. Should any photos be used where participants can be recognized, participants must always be asked in advance and must give their consent.

Information letter

The information letter should include the following:

- a short description of the project and its aims,
- the name and details of a contact person,
- a description of the collection, analysis and storage of the data,
- a description of how privacy, confidentiality and anonymity will be ensured,
- a statement that the data will be used for this project only,
- a reminder for the participants that their participation is solely on a voluntary basis and that they can withdraw at any time without any reason and without any consequences,
- a reminder that they can pull their data from the results if they wish to do so,
- an explanation of the risks and benefits of participation, and,
- a note on post-project management such as what will happen with the results of the research, what will happen with the collected data, how can the participants be informed about the results

Consent form

Through their signature of the consent form the participants

- confirm that they have read and understood the information letter,
- confirm that they understand their participation to be voluntary and that they can withdraw at any time, without giving any reason,
- confirm that any information given by them may in anonymized form be used by the research team in reports, articles or presentations,
- confirm that they understand that all data about them will be confidential and that their identity will not be disclosed outside the research team, and.
- agree to take part in the study.

6.5 Sample confirmation form for informed consent

The following sample document can be used by the LILY partners in informing participants about the various LILY research activities.

Sample Informed consent form –Project LILY
[This consent form will be supplemented by information material presenting the project in easily understood terms to the potential participants.]

Dear _,

The [Name of organization] under the leadership of Professor [Name] invites you to participate in interviews, a user panel and in user trials in a technology research and development project called LILY (Advanced Support for Independent Living; Human Life Cycle Approach in Senior Housing). The aim of the LILY project is to develop advanced ICT support for independence and participation of older people in the self-serve society. The project is a European cooperation effort and it is coordinated by the University of Oulu.

In order to develop an acceptable and usable system for older people, the project group at the [name of institute] plans to collect information [ADD METHODS; for example through interviews, discussions in user panels and user trials]. You have been selected as a possible participant in this study because [provide reason; for example: your home town is actively involved in the project].

If you decide to join in the activities of the LILY project, Professor [Name] and [his/her] team will invite you to participate in [list activities planned for users; for example, interviews, meetings with other older people and persons involved in care, and in testing functional prototypes developed in the project]. [Describe what is expected of users in terms of time; for example, the interviews will last approximately 1-1,5 hours and the meetings 1,5-2 hours. The duration

of the testing of prototypes varies from short trials in laboratory conditions to longer real-life tests in your home.] [Expectation of risks and benefits; for example, on one hand, no risks or inconveniences are expected from your participation, on the other hand, the project cannot guarantee, that you will receive any benefits from this study.]

[Confidentiality aspects; for example, any information that is obtained in connection with this study and that can be identified with you will remain confidential. If photos or videos are made, your permission for doing so will be asked for separately. Your permission will also be asked for using any photos or videos where you could be recognized outside of the project (for example, in a conference or a scientific publication)].

[Compensation] Your travel costs to and from interviews, meetings, and user trials will be compensated. [Optional in case any risks of injury will be identified in the process of the project: you will be insured for the duration of your participation in the user trials.]

If you decide to participate, you are free to withdraw your consent and to discontinue participation at any time without providing a reason. From time to time, you will be asked by the project team if you wish to continue as a participant in the project.

If you have any questions, please ask us. If you have any additional questions after signing this form or during your participation, Professor [Name] will be happy to answer them. You can reach [him/her] at: [address, telephone number, e-mail address].You will be given a copy of this form to keep.

Your signature below indicates that you have decided to participate in the study. It also confirms that you have read and understood the information above and in the project information provided to you by the project team. The project team has answered any of your questions to your satisfaction. You are also aware of the fact that you can contact Professor [Name] with any further questions and can withdraw your consent any time without providing a reason.

Date and place

_____

_____

Signature of participant and clarification of name

_____

Signature of investigator and clarification of name

7. Legislation and policies

This deliverable on ethics and user involvement concludes with a listing of a number of central guidance and legal documents that the partners are encouraged to review when planning their research activities that involve older persons.

7.1 European Union

7.1.1 Data protection and privacy

- Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data
- 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 (Directive on privacy and electronic communications)
- Directive 97/66/EC of the European Parliament and of the Council of 15 December 1997 concerning the processing of personal data and the protection of privacy in the telecommunications sector

7.1.2 Ethical issues and research

- Directive 2001/20/EC of the European Parliament and of the Council of 4 April 2001 on the approximation of the laws, regulations and administrative provisions of the Member States relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use
- Commission Directive 2005/28/EC of 8 April 2005 laying down principles and detailed guidelines for good clinical practice as regards investigational medicinal products for human use, as well as the requirements for authorisation of the manufacturing or importation of such products

7.2 France

7.2.1 Data protection and privacy

- Law n°78-17 of 6 January 1978
- Law n°2004-801 of 6 August 2004 (modifying Law n°78-17 of 6 January 1978)
- Decree n°2005-1309 of 20 October 2005

7.2.2 Laws regulating health care and social care

- Law no 2004-810 of 13 August 2004 concerning healthcare insurance
- Law n°2002-303 on patients' rights and the quality of the health system
- Law n°2005-370 concerning the patients' rights at the end of life:

7.2.3 Relevant committees, agencies and organizations

- Comités de Protection des Personnes (Committees for the Protection of Persons, CPPs)
- Commission Nationale de l'Informatique et des Libertés (National Commission on Informatics and Liberty, CNIL)
- Comité Consultatif National d'Ethique pour les Sciences de la Vie et de la Santé (National Consultative Ethics Committee on Health and the Life Sciences)
- Conseil National de l'Ordre des Médecins (French National Medical Council, CNOM)

7.3 Finland

7.3.1 Data protection and privacy

- Personal Data Act (523/1999)
- Act on the amendment of the Personal Data Act (986/2000)

7.3.2 Laws regulating health care and social care

- Laki ikääntyneen väestön toimintakyvyn tukemisesta sekä iäkkäiden sosiaali- ja terveyspalveluista 28.12.2012 (980/2012) (Senior Citizens Services Act) into force 1.7.2013
- Terveydenhuoltolaki 30.12.2010/1326 (Health Care Act)
- Sosiaalihuoltolaki 17.9.1982/710 (Social Welfare Act)
- Laki potilaan asemasta ja oikeuksista 17.8.1992/785 (Act on the Status and Rights of Patients)
- Laki sosiaalihuollon asiakkaan asemasta ja oikeuksista 22.9.2008/812(Law for social care clients' status and rights)
- Laki sosiaali- ja terveydenhuollon asiakasmaksuista 3.8.1992/734 (Law for health care patient and social care clients payments about care and service)
- Laki sosiaali- ja terveydenhuollon asiakastietojen käsittelystä 9.2.2007/159 (Law for hcp and scc client information handling/processing)
- Laki sosiaali- ja terveydenhuollon suunnittelusta ja valtionosuudesta 3.8.1992/733 (Law for planning and funding health- and social care)
- Laki sosiaali- ja terveydenhuollon palvelusetelistä 569/2009 (Act on the health and social care service voucher)

7.3.3 Relevant committees, agencies and organizations

- The National Advisory Board on Social Welfare and Health Care Ethics (ETENE) (http://www.etene.fi/en)
- Data Protection Board (http://www.om.fi/en/Etusivu/Ministerio/Neuvottelujalautakunnat/Tietosuojalautakunta)
- National Committee on Medical Research Ethics TUKIJA (http://www.tukija.fi/en/)
- National Advisory Board on Research Ethics (http://www.tenk.fi/en/index.html)
- The Association of Finnish Local and Regional Authorities http://www.localfinland.fi

7.4 Austria

When applicable; according to the work plan LILY user involvement activities are not planned to be held in Austria.

7.4.1 Data Protection and Privacy

- Datenschutzgesetz 2000 (Federal Act governing the protection of personal data)
- Gesundheitstelematikgesetz (Federal Act governing health telematics)
- Medizinproduktegesetz (Federal Act governing medical products)

7.4.2 Relevant committees, agencies and organizations

- Datenschutzkommission (Data Protection Commission)
- Ethikkommissionen (Research Ethics Commissions)
- Bioethikkommission beim Bundeskanzleramt (Austrian Bioethics Commission)

7.5 Further Key Documents

- Charter of Fundamental Rights of the European Union
- European Convention on Human Rights and Biomedicine
- Geneva Declaration of Principles and Plan of Action (Ethical Dimensions of the Information Society)
- Tunis Agenda for the Information Society
- Universal Declaration of Human Rights
- WMA Declaration of Helsinki - Ethical Principles for Medical Research Involving Human Subjects

8. Concluding words

The deliverable at hand forms the D1.1 and D1.2 of the LILY project and outlines the main research ethical issues to be taken into account in conducting research with older persons in the LILY context. The ethical guidance during the project may need to be adjusted in case new, unaccounted for ethical issues surface. Should new ethical issues be encountered, they will be documented and reported in subsequent deliverables in the WP1.

9. Literature

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