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Miraculous-Life
Miraculous-Life for Elderly Independent Living

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Table of Contents

Abbreviations

Abbrev.	*Description*
AAL	Ambient Assisted Living
CFREU	Charter of Fundamental Rights of the European Union
DoH	Declaration of Helsinki
FADP	Federal Act on Data Protection
FARHB	Federal Act on Research involving Human Beings
LIPAD	Loi sur l'information du public, l'accès aux documents et la protection des données personnelles
UDHR	Universal Declaration of Human Rights
WP	Work package

Executive Summary

The deliverable D1.3 “Ethical, Privacy, Legal Considerations and Deontological practice” has been written for the WP1 “End Users Needs Analysis and Functional Specification”.

The overall aim of the Miraculous-Life project is to design, develop and evaluate a Virtual Support Partner that by analogy to a real life human partner, considering emotional understanding and responding, will attend to the needs of the elder while he goes about his normal daily life activities in the totality of his home and provide implicit support and also safety.

This report analyse legal, ethical, deontological considerations that should be taken into account during the whole duration of project by both (1) technical partners while designing and developing the system and (2) end-user partners while collecting data and testing the Miraculous-Life prototypes. Firstly, legal, ethical and deontological considerations concerning practice in research involving human being will be evaluated. These guidelines are particularly relevant for end-user partners. In a second step, legal considerations concerning data protection and security will be assessed. These guidelines are relevant for both end-user and technical partners: technical partners have the duty to design technological solutions respectful of the national and international law concerning data protection and storage; while investigators must ensure the privacy of participants and data confidentiality. Thirdly, ethical considerations concerning behavioural analyses technologies will be discussed. These recommendations are relevant for both end-user and technical partners: on the one hand, technical partners should consider the social and ethical implications of the Miraculous-Life technologies; on the other hand end-users partners should involve users in order to evaluate the ethical acceptability of the system. Finally, considerations about privacy and security requirements of the Miraculous-Life system will be discussed; knowing that the components that guarantee the safe handling of private sensitive data will be designed and developed as an integral part of the system components in WP5.

1 About this Document

1.1 Role of the deliverable

This deliverable serves as a reference and provides guidelines in terms of ethical, deontological and legal issues that must be considered by all projects partners (technical and end-users) during the whole duration of the Miraculous-life project. This report includes also a detailed analysis regarding: (1) ethical, legal and deontological considerations concerning practice in research involving human being, (2) legal considerations concerning data protection and security, (3) ethical considerations concerning behavioural analyses technologies, (4) privacy and security requirements of the Miraculous-Life system.

1.2 Relationship to other Miraculous-Life deliverables

The deliverable is related to the following Miraculous-Life deliverables:

Deliv:	*Relation*
D1.1, D1.2, D1.4, D6.1, D6.2, D6.3	The behaviour adopted by Miraculous-Life researchers during data collection will be compliant with the deontological guidelines presented in this report.
D2.1, D2.2, D2.3, D2.4, D4.2	Technical partners should evaluate the ethical acceptability of technologies designed and developed. In this report we propose guidelines that could help them to make moral decisions.
D5.1	This report is strongly related to the D5.1 “Specification of overall system architecture and security and privacy infrastructure”. In this deliverable, the components that guarantee the safe handling of private sensitive data will be designed and developed.

2 Ethical, legal and deontological considerations concerning practice in research

2.1 Introduction

This chapter discusses the ethical, legal and deontological considerations concerning practice in research. Since the Miraculous-Life project envisages data collection from human beings; ethical and legal issues plays a major role. Ethical reflexions may conflicts with legal regulations. In such cases, law has a higher priority.

2.2 General ethical guidelines

The General ethical guidelines of the Miraculous-Life project are the respect for human dignity, integrity, autonomy, freedom.

The dignity of the human being is considered as a fundamental, inherent, inalienable, universal right. The first Article of the Universal Declaration of Human Rights (UDHR) declares that “All human beings are born free and equal in dignity and rights. They are endowed with reason and conscience and should act towards one another in a spirit of brotherhood”. The first Article of the Charter of Fundamental Rights of the European Union (CFREU) also states that “human dignity is inviolable. It must be respected and protected”. No rights may be exercised with the intent of violating the dignity of another person.

Human dignity is closely linked to human integrity. According to Cox, La Caze and Levine (2013), five philosophical approaches were advanced in order to assess the concept of human integrity: (1) the integrity as self-integration, (2) the integrity as maintenance of identity, (3) the integrity as standing for something, (4) the integrity as moral purpose, and (5) the integrity as a virtue. Note that the third article of the CFREU proclaims that “everyone has the right to respect for his or her physical and mental integrity”.

The principle of autonomy refers to the right to be a self-governing agent; i.e. the right to make an informed, independent, un-coerced choice. Human beings have the right to make decisions and take actions based on its own beliefs and values.

According to the UDHR and the CFREU, everyone has the right to freedom of thought, conscience and religion, freedom of opinion and expression, and freedom of information. One person’s exercise of freedom may conflict with the freedom of others or with ethical principles. In such cases, freedom of others and ethical principles have a higher priority.

Finally, all the technologies designed and developed in the Miraculous-Life project will be respectful of the human dignity, integrity, autonomy and freedom. All the data collected about the users of the Miraculous-Life system will not be directly used for commercial purposes.

2.3 Legal considerations concerning practice in research

It’s the duty of end-user organisations participating in the Miraculous-Life project to respect the legislation concerning deontological practice in research. This chapter gives an overview on the legal requirements that are relevant for the Miraculous-Life system evaluation.

2.3.1 Europe

The Declaration of Helsinki (DoH) is a set of ethical principles regarding research involving human being. According to the seventh Article of the DoH, research involving human being is “subject to ethical standards that promote and ensure respect for all human subjects and protect their health and rights”. Note that research subjects’ rights and

interests must always take precedence over the research's goals (art. 8). It is also the duty of investigators to "to protect the life, health, dignity, integrity, right to self-determination, privacy, and confidentiality of personal information of research subjects" (art. 9). There are also a variety of other European directives and regulations concerning deontological practice in research involving human being:

- Good scientific practice in research and scholarship European Science Foundation Policy Briefing (http://www.esf.org/fileadmin/Public_documents/Publications/ESPB10.pdf)
- Ethical Guidelines developed by Social Research Association (recommended to used by Disability Rights Commission, UK)
- Directive 2001/20/EC on the implementation of Good Clinical Practice in the conduct of clinical trials on medicinal products for human use (http://www.eortc.be/Services/Doc/clinical-EU-directive-04-April-01.pdf)

2.3.2 Netherlands

The following legislation and regulations concerning ethics in science, apply in the Netherlands:

- The Medical Research Involving Human Subjects Act (Wet medisch-wetenschappelijk onderzoek met mensen (WMO)): http://wetten.overheid.nl/BWBR0009408/
- 'The Netherlands Code of Conduct for Scientific Practice', from the Association of Universities in the Netherlands: http://www.vsnu.nl/files/documenten/Domeinen/Onderzoek/The_Netherlands_Code_of_Conduct_for_Scientific_Practice_2012.pdf

Above mentioned act and code are both based on the Helsinki Declaration drafted by de World Medical Association. Although these legislation and regulations are not fully applicable to Miraculous-Life, as it is not medical research or research in which the participants are subjected to specific behaviour, the principles of the WMO and the Code can be applied.

The most important principles are: (1) scrupulousness, (2) reliability, (3) verifiability, (4) impartiality and (5) independence.

Derived from these principles the most important applicable points are first and foremost the interest and well-being of the participants, their voluntary participation and the possibility to withdraw from Miraculous-Life at any time.

2.3.3 Switzerland

In Switzerland, research on human beings is regulated by the Federal Act on Research involving Human Beings (FARHB). According to the first article of the FARHB, the purpose of this Act is to protect the dignity, privacy and health of human beings involved in research. This Act is also designed to: create favourable conditions for research involving human beings, help to ensure the quality and the transparency of research involving human beings. The principles of this Act also includes: the primacy of individual interests (art. 4), the non-discrimination (art. 6), the consent (art. 7) and the right to receive information (art. 8). The principle of subsidiarity is described in the article 11: "A research project involving persons may only be carried out if equivalent findings cannot be obtained by other means". According to the article 12 of the FARHB, the risks and burdens for the participants must be minimised and must not be disproportionate to the expected benefits

of the research project. The article 15 regulates for safety and protective measures: researchers have the duty to take all the measures required in order to protect the participants, before the research project begins. According to the article 16 of the FARHB, subjects may only be involved in a research project if they have given their informed written consent. In addition, participants must receive oral and written information about the research project, the risks and burdens, the expected benefits of the project, the measures to ensure and the participant rights.

2.4 Deontological issues

The behaviour adopted by Miraculous-Life researchers will be compliant with the general ethical guidelines (see chapter 2.2) and the legal dispositions concerning practice in research (see chapter 2.3). This chapter gives an overview on the deontological general directives adopted by researchers in the Miraculous-Life project.

2.4.1 Information provision to participants

Information about the project (goals, risks, burdens, benefits) must be provided by researchers in advance. Participants will be also provided with an informative brochure explaining the aims of the Miraculous-Life project (see annex 1). Researchers have also the duty to ensure that participants understand the information provided by investigators.

2.4.2 Principle of voluntariness

According to the article 25 of the DoH, “participation by individuals capable of giving informed consent as subjects in medical research must be voluntary”. The voluntary consent of the participant is absolutely mandatory. Participants are also free: (1) to decline to participate to the study for any reason, (2) to refuse to answer any individual question, and (3) to withdraw the evaluation or the trial at any time without providing a reason and without incurring displeasure, disadvantage and penalty.

2.4.3 Informed consent

According to Eyal (2012), there are seven informed consent rationales: (1) protecting participants' health and welfare, (2) encouraging participants’ autonomy, (3) preventing abusive conduct, (4) contributing to the instauration of trust, (5) ensuring self-ownership, (6) promoting non-domination, and (7) protecting participants’ sense of personal integrity.

Informed consent is mandatory prior to any data collection, storing, processing, and transferring. Each participant will have to sign an informed consent form (see annex 2). The latter will: (1) describe the aims and the methods of the study, (2) clearly state the nature of the participant’s involvement, (3) inform about the sources of funding and about any possible conflicts of interests, (4) illustrate potential benefits, risks and discomforts, (5) announce the measures that will be taken to ensure privacy, anonymity and confidentiality of data, (6) highlight the principle of voluntariness and the right to withdraw the evaluation or the trial, (7) provide institutional affiliation of the investigators and all the coordinates to contact them.

When a potential participant is not able to sign the informed consent form, a responsible relative or a care professional may sign on his / her behalf.

Informed consent form will be signed in two copies: the first one will be given to the participant; the second one will be securely stored by investigators. Stored signed informed consent forms will be available exclusively for the responsible evaluation manager and for the responsible ORBIS and MRPS investigator and will be destroyed once the study is concluded.

2.4.4 Risk minimization for participants

Risks for participants will be assessed and satisfactorily managed. According to the Article 11 of the DoH, measures will be implemented to minimize risks of emotional, psychological or physical harm for participants. Investigations will be conducted by partners with appropriate scientific education, training and qualification; minimizing risk for participants.

Risks will be also continuously monitored, assessed and documented by investigators; as provided for in Article 17 of the DoH. If there are risks for the participant, investigators will have the duty to suspend or terminate the evaluation or the trial. Finally, note that "when the risks are found to outweigh the potential benefits or when there is conclusive proof of definitive outcomes, physicians must assess whether to continue, modify or immediately stop the study" (art. 18 of the DoH).

2.4.5 Anonymity, confidentiality and data security

Every precaution will be taken in order to protect participants' anonymity and guarantee the confidentiality of their personal information, as provided for in Article 24 of the DoH.

The anonymity of participants will be respected: all participants have the right to expect that the information they provided will be kept confidential and, if published, will not be identifiable as theirs. Personal information regarding participants will be also treated as confidential. No personal data related to participant identity will be stored locally or remotely. If anonymity or confidentiality cannot be guaranteed, participants will be informed before their agreement.

To maximise anonymity, confidentiality and data security: (1) pseudonyms and codes will be used to identify participants, (2) collection of confidential data will be minimized, (3) confidential data purpose will be identified by investigators before collecting data, (4) data will be stored in encrypted files which will be accessible only by authorized investigators, (5) technological measures will ensure an appropriate protection of confidential data. System and network operators will not be able to access or change confidential data without user agreement, (6) data will be maculated once the project is concluded.

Note that legal considerations concerning data protection and security can be found on the chapter 3.

2.4.6 Test environments

Different test sites located in Netherland (Orbis) and in Switzerland (MRPS) will be involved in the Miraculous-Life project. User needs and requirements analysis and user pre-trials evaluation will be realized in a laboratory setting and/or in the users' apartment, while the trials will be performed in the users' apartment. As the prototypes will be installed in the users' apartment, specific ethical and legal issues will be considered. Finally, investigators will ensure that test locations are safe and comfortable for both involved participants and caregivers.

2.4.7 Participant selection

Inclusion and exclusion criteria for participation in the study will be defined by technical and usability experts of the project's consortium. Based on these criteria, ORBIS and MRPS investigators will select participants for the study. Investigators will (1) ensure that the selection process of participants is fair, non-discriminatory, and unbiased and (2) select participants who can potentially provide useful and rich data about the phenomenon under investigation.

3 Legal considerations concerning data protection and security

3.1 Introduction

This chapter describes legal considerations concerning data protection and security. Users' privacy and data security are one of the main concerns of Miraculous-Life project. With the development of ICT applications in the health sector, assuring patient privacy and data security is progressively becoming a complex task. In AAL projects, every precaution must be taken to ensure end-user's privacy and security.

All Miraculous-Life partners are affected by laws and regulations related to data protection:

- On the one hand, technical partners have the duty to design solutions in full compliance with both national and European legislations concerning (sensible) data protection and storage. Note that the fourth chapter of this document describes the privacy and security general requirements of the Miraculous-Life system; knowing that components that guarantee the safe handling of private sensitive data will be designed and developed as an integral part of the system components in WP5.
- On the other hand, end-users organisations have the duty to ensure the privacy of research participants and the data security, and this in full compliance with both national and European legislations concerning data protection.

This chapter gives an overview on the legal requirements that are relevant for the Miraculous-Life project.

3.2 Europe

- 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 (need of explicit consent by the person on whom data is going to be collected) http://europa.eu/legislation_summaries/information_society/data_protection/l14012_en.htm)
- Council of Europe, European treaties, ETS no. 108, convention for the protection of individuals with regard to automatic processing of personal data, with amendments and additional protocol (http://conventions.coe.int/Treaty/en/Treaties/Html/108.htm)

3.3 The Netherlands

The most important Ducth act concerning data protection is the 'Wet Bescherming Persoonsgegevens' (Dutch Protection of Personal Details Act) http://wetten.overheid.nl/BWBR0011468/, which is the Dutch implementation of the European Directive 95/46/EC, defines rules and procedures how organisations have to deal with personal details. The Dutch institute College Bescherming Persoonsgegevens (CBP) is the data protection agency that sees to it that rules are obeyed by organisations and companies. The law defines who is allowed to have access to which data and for which purpose in line with the principles set by the directive: transparency, legitimate purpose and proportionality. Also people are offered certain rights over data held about them such as the right to know what is held about him and the right to have errors corrected.

Applied to Miraculous this means that collection and processing of data must meet the conditions defined by law and that the elderly or assisted person in Miraculous, or his/her legal representative, can exercise some level of control over the information.

The target group of Miraculous consists of a group of healthy elderly or with light physical or mental health problems, which may expand the scope of Miraculous towards healthcare. In such case the 'Wet Geneeskundige Behandelingsovereenkomst' (Dutch Medical Treatment Agreement Act) may apply, which mandates that patients be properly informed regarding their treatment, mandates dossier keeping and patient related rights. See: http://wetten.overheid.nl/BWBR0007021/. For privacy the 'Wet Bescherming Persoonsgegevens' remains applicable.

3.4 Switzerland

Given that Switzerland is a federal republic, data protection is governed both by federal and cantonal law. According to the article 44 of the Federal Constitution of the Swiss Confederation, the Cantons shall implement federal law in accordance with the federal legislations. As a result, the cantonal law is in principle similar to the federal one.

On the federal level, data protection is governed by the Federal Act on Data Protection (FADP) of 1992. The FADP applies to the processing of data pertaining to natural persons and legal persons by private person and federal bodies (art. 2). As private person, investigators are subjects to this law. The principles of the FADP (art. 4) states that:

1. Personal data may only be processed lawfully,
2. Its processing must be carried out in good faith and must be proportionate,
3. Personal data may only be processed for the purpose indicated at the time of collection, that is evident from the circumstances, or that is provided for by law,
4. The collection of personal data and in particular the purpose of its processing must be evident to the data subject,
5. If the consent of the data subject is required for the processing of personal data, such consent is valid only if given voluntarily on the provision of adequate information. Additionally, consent must be given expressly in the case of processing of sensitive personal data or personality profiles.

According to the article 7 of the FADP, personal data must be protected against unauthorised processing through adequate technical and organisational measures. The article 8 of the FADP states that any person may request information from the controller of a data file as to whether data concerning them is being processed. The controller of a data file must notify the data subject: (1) of all available data concerning the subject in the data file, including the available information on the source of the data; (2) the purpose of and if applicable the legal basis for the processing as well as the categories of the personal data processed, the other parties involved with the file and the data recipient. In addition, anyone who processes personal data must not unlawfully breach the privacy of the data subjects in doing so (art. 12, FADP). In particular, he must not: process data pertaining to a person against that person's express wish without justification and disclose sensitive personal data or personality profiles to third parties without justification. Finally, the article 14 of the FADP states that the controller of the data file is obliged to inform the data subject of the collection of sensitive personal data or personality profiles. The data subject must be notified of the controller of the data file, the purpose of the processing and the categories of data recipients if a disclosure of data is planned.

In the Canton of Geneva, data protection is governed by the « Loi sur l'information du public, l'accès aux documents et la protection des données personnelles (LIPAD) » of 2001. The LIDAP applies to the cantonal and communal public-law institutions (art. 3, LIDAP), including the University of Geneva and the Maison de Retraite du Petit-Saconnex.

The articles 35 and seq. of the LIPAD governs for data protection and processing. According to the article 35 of the LIDAD, public-law institutions can process personal data or personality profiles only if this processing is necessary for the fulfilment of their lawful duties. In addition, the explicit, free and informed consent of the person concerned is mandatory prior to any data processing. Public-law institutions must also ensure that the processing of personal data is (1) relevant and necessary to the performance of their lawful duties; (2) accurate and, where necessary updated and supplemented (art. 36, LIDAD). The article 37 of the LIDAD governs for the security of personal data: (1) personal data should be protected by appropriate organizational and technical measures against unlawful processing; (2) public-law institutions must take the necessary measures to ensure the availability, integrity and confidentiality of the personal data. According to the article 38 of the LIPAD, the collection of personal data must be clearly recognizable by the concerned person. The article 39 of the LIPAD governs the transfer of personal data. This law distinguishes four entities that can receive personal data: (1) a public-law institution subject to the LIPAD law, (2) a public-law institution or a Swiss corporation not subject to the LIPAD law, (3) a foreign corporation or foreign public-law institution, (4) a third person or entity subject to the private law. Note that the LIPAD defines different directives for the transfer of personal data, depending on the recipient. According to the article 40 of the LIDAP, public-law institutions must destroy or anonymize the personal data that they no longer need to perform their lawful duties. The article 41 of the LIPAD states that public-law institutions are entitled to process personal data for general statistical purposes, scientific research and for planning or evaluation of public policies provided that: (1) the processing of personal data is necessary for these purposes, (2) data will be destroyed or anonymized as soon as the purposes of the data processing allows, (3) data collected will be not communicated to others institution or person, (4) results will be presented such a manner that the data source may not be identified.

The articles 44 and seq. of the LIPAD governs for the rights of the person concerned. According to the article 44 any person concerned has the right to be informed by whom their information is handled. In addition the person concerned has the right to access to the stored data related to him or her. Finally, the person concerned has the right to ask that the information related to him is destroyed or corrected (art. 47).

4 Ethical considerations concerning behavioural analyses technologies

4.1 Introduction

In this chapter, we discuss ethical considerations concerning behavioural analyses technologies. The overall aim of the Miraculous-Life project is to design, develop and evaluate a Virtual Support Partner that by analogy to a real life human partner, considering emotional understanding and responding, will attend to the needs of the elder while he goes about his normal daily life activities in the totality of his home and provide implicit support and also safety. For this purpose, technological partners will design and develop a number of technologies for user behaviour analysis and emotion recognition based on facial expression, prosody cues, gestures and context. On the one hand, these advanced technologies have many potential constructive uses in AAL systems. On the other hand, using such technologies raises new ethical questions.

4.2 Ethical acceptability of the Miraculous-Life system

Reynolds and Picard (2005) suggested three questions that designers should ask themselves in order to assess the impact of affective computing systems on users:

1. *Could a user be emotionally manipulated by a program with the capability to recognize and convey affect?*
2. *Should an affective system try to change the emotional state of a user?*
3. *Would a system that allows surveillance of previously invisible affective signals invade privacy?*

According to the authors, a large number of dimensions come in play in answering those questions. They also identified twenty-three dimensions that could help designers to evaluate the ethical acceptability of affective technologies. In the following table, we repot these dimensions with the definitions provided by the authors. For each dimension, we discuss issues concerning the Miraculous-Life system.

Dimension	*Definition*	*Issues for Miraculous-Life system*
(1) Whom	The individual or individuals who receive the communicated affective message.	Primary end-user. Elderly will receive indirectly their own affective information through the feedback provided by the Virtual Support Partner. Secondary end-user: to what extent, under what conditions and in what ways caregivers should receive the affective and behavioural information generated by the primary end-user (and detected by the system)?
(2) What	That acts as a transmitter or receiver for the communicated affective message.	“Emotion fusion component” of the Miraculous-Life system.
(3) Goal relationship	The degree of conflict between the goals of the sender and receiver, which can be (but does not have to be) modelled from a game-theoretic perspective.	Cooperative. Primary, secondary and tertiary end-users of the system should have common goals: (1) promote the well-being of the elderly, (2) support the elderly to remain longer independent at home.

(4) Power relationship	Role that reflects the ability of either source or destination to alter the political, economic, or social situation of the other.	Peer. The Miraculous-Life system may not be used to alter the political, economic or social situation of the primary end-users.
(5) Genre of Emotion	Model used by the system to describe and encode emotion.	Facial expression, prosody, gesture, context information.
(6) Valence	Classification of transmitted emotion using an axis with positive or negative poles to describe feeling state.	Both positive and negative emotions could be detected, computed and potentially transmitted by the system to secondary end-users.
(7) Demeanor of Recipient	Emotional state of the message destination	Primary and secondary end-users will experience a whole range of emotions during the test phase.
(8) Gender	Classification of either message source or destination based on reproductive role	The system will be used by women and men. Note that, in western society, gender stereotypes prescribe that women are more emotional than men (…). This stereotype may potentially impact on how women and men will assess the Miraculous-Life system in terms of ethical acceptability.
(9) Ethnicity	Classification of either message source or destination based on racial or cultural identity	Since the end-users sites are in Netherland and in Switzerland, the system will be principally evaluated by European elderly and European caregivers. It would be interesting to involve in the trials users from different ethnic backgrounds: cultural identity may also potentially impact on how end-users will assess the Miraculous-Life system in term of ethical acceptability.
(10) Age	Classification of either message source or destination based on duration of life.	Primary end-users: advanced age. Secondary end-users: middle-aged. Note that the age difference between cohorts may potentially impact on how primary and secondary end-users will assess the Miraculous-Life system in term of ethical acceptability.
(11) Culture	Cultural context of communication and of either message source or destination.	The Hofstede Centre (http://geert-hofstede.com) proposes six dimensions along which cultural values could be analysed: (1) Power Distance Index, (2) Individualism versus Collectivism, (3) Masculinity versus Femininity, (4) Uncertainty Avoidance Index, (5) Pragmatic versus Normative, and (6) Indulgence versus Restraint. Netherland and Switzerland share the following cultural values: a low score on the power distance dimension; a relatively high score on the uncertainty avoidance dimension; a high score on the individualism, pragmatic and indulgence dimensions. Interestingly, the two countries differ in the masculinity/femininity scale: while Switzerland is a masculine society (i.e. characterised by competition, achievement and success), Netherland is a feminine society (i.e. characterised by caring for others and quality of life). This cultural difference may potentially impact on how Swiss and Dutch end-users will assess

		the Miraculous-Life system in terms of ethical acceptability.
(12) Risk	Potential impact of communication on goals of message source or destination.	No risks are identified at this early stage of the project.
(13) Symmetry	Information or power balance between users of communication system.	One-sided. Secondary end-users will potentially receive the affective message generated by primary end-users (and detected by the system); but not vice versa.
(14) Trust	The degree to which the message source trusts either the destination or the channel.	The success of the Miraculous-Life project will depend on users' trust in the system. Technologies such Kinect may also be perceived as intrusive and produce resentment. Necessary measures will be taken in order to (1) evaluate and (2) increase trust of end-users on the Miraculous-Life technologies and security policy.
(15) Designer	Person or organization who created the system, that mediated the communication of affect.	Miraculous-Life's technical partners.
(16) Experimenter	The person who conduct an experiment that evaluates the ethical acceptability of communication system.	Orbis (NL), MRPS (CH)
(17) Time	When the system that mediates the communication of affect is used.	The first prototype will be evaluated on the month 8 of the Miraculous-Life project.
(18) Informed Consent	Does message source voluntarily consent to transmission of affective signals?	The research participants will sign an informed consent form. Participants will be also provided with an informative brochure explaining the aims of the Miraculous-Life project.
(19) Security	Classification of security level of communication system or encoded signal.	See chapter 5.
(20) Control	Degree to which message source can control the transmission of affective signals.	The system will assess automatically the emotion of the primary end-user, allowing an empathic conversation with the primary end-user. In principle, the system should not disclose affective or behavioural information to any third party without the permission of the primary end-user. Nevertheless, the system should disclose behavioural information to formal caregivers if there are safety concerns for the primary end-user.
(21) Feedback	Can the message source access the transmitted affective signal?	Primary end-users will access indirectly to their own affective information through the feedback provided by the Virtual Support Partner during conversation.
(22) Transparency	Are the workings of the	Every project deliverable – including software –

	system that mediates the communication of affect visible for inspection, and by whom?	undergoes a three-step quality check. In the first step, the Quality Assessor (i.e. a WP-external quality reviewer affiliated at one of the partners) produces a comprehensive review of the technical quality of the deliverable. In the second step, the deliverable is revised by authors according to the recommendations of the Quality Assessor. The Quality Controller (assigned for every deliverable on a yearly basis) checks to which extend the deliverable implements the review. Finally, in the third step, the Quality Manager (usually the WP leader) undertakes a final check of the deliverable before delivering it to the European Commission. Transparency will be ensured by this quality check.
(23) Proximity	Distance between message source and message destination.	The physical distance between primary and secondary end-users should be in principle low.

According to Reynolds and Picard (2004), designers should involve users to evaluate the ethical acceptability of affective technologies: “an important growing concern (…) is how users feel about such technology – whether it feels respectful of their privacy and other needs, and on what basis it is acceptable or not. Thus, the emphasis here is not on what can be done, but rather on helping illuminate what users think should be done.” Reynolds (2005) also designed a questionnaire to assess users’ perception on the ethical acceptability of affective technologies. Six items of this questionnaire could be adapted in order to assess the ethical acceptability of the Miraculous-Life system during the whole project duration:

(1) From 1 to 7, do you think that the Miraculous-Life system is:

1	2	3	4	5	6	7
Unethical			Indifferent			Ethical

(2) From 1 to 7, do you think that the Miraculous-Life system is:

1	2	3	4	5	6	7
Invasive			Indifferent			Respectful

(3) From 1 to 7, does the Miraculous-Life system make you feel:

1	2	3	4	5	6	7
Comfortable			Indifferent			Uncomfortable

(4) From 1 to 7, do you think the Miraculous-Life system is:

1	2	3	4	5	6	7
Moral			Indifferent			Immoral

(5) From 1 to 7, the Miraculous-Life system make you feel:

1	2	3	4	5	6	7
Suspicious			Indifferent			Trustful

(6) From 1 to 7, do you feel the Miraculous-Life system is:

1	2	3	4	5	6	7
Fair			Indifferent			Unfair

5 Privacy and security requirements of the Miraculous-Life system

5.1 Introduction

This chapter specifies the privacy and security requirements for the Miraculous-Life system and services. Jensen et al. (2009) identified seven reusable security requirements for healthcare ICT applications using the European Data Protection Directive as a starting point. We consider that six of these requirements represent an interesting basis for AAL and, by extension, for Miraculous-Life project: (1) the identification and authentication requirements, (2) the authorization requirements, (3) the integrity requirements, (4) the privacy requirements, (5) the security auditing requirements and (6) the survivability requirements.

5.2 Identification and authentication requirements

The Miraculous-Life system should identify and verify the identity of all of its human users before allowing them access to his resources. In order to meet this requirement, the system should include an authentication infrastructure. Two login systems should be designed: the first one should identify and verify the identity of the primary end-user on the front-end application; the second one should identify and verify the identity of the secondary end-user on the back-end application.

5.3 Authorization requirements

The Miraculous-Life system should use access levels in order to define what users can do. Only authorized users will be able to access, control, configure the device and install new services. Furthermore, the system should verify the authorization level of users before access to sensitive data can be given: only user with an appropriate access rights will be able to open, edit and save sensitive data.

5.4 Integrity requirements

The Miraculous-Life system should support integrity protection of sensitive personal data while it is stored. All personal data will be encrypted by default in order to ensure security. The system should also be able to detect unauthorized manipulation of data that is being transmitted. Measures will be taken in order to protect from illegal access by malicious programs and malicious users. An intrusion detection system will prevent and reveal system attacks from internal or external sources.

5.5 Privacy requirements

The Miraculous-Life system must protect any stored sensitive personal data from unauthorized access. Furthermore, personal sensitive data must be confidentiality protected while transmitted over open, untrusted communication lines. Note that the components that guarantee the safe handling of private sensitive data will be designed and developed as an integral part of the system components in WP5.

5.6 Security auditing requirements

The Miraculous-Life system should be able to log security incidents, such as failed login attempts or unauthorized access attempts to services in order to uncover and trace system abuse. In addition, the system should be able to log activities related to sensitive data manipulation.

5.7 Survivability requirements

The designers should ensure the survivability of the Miraculous-Life system. Firstly, the Miraculous-Life system should check for correctness, meaningfulness and security of input data in order to reduce threats represented by malicious content. In addition, multiple level of security should be designed in order to avoid a “single point of failure”. Finally, data freshness should be controlled to prevent the chances of replay attacks.

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Appendix A Informative brochure

PARTICIPANT INFORMATION FORM

PROJECT PRESENTATION

The main aim of the Miraculous-Life project is to design, develop and evaluate an innovative technological solution attending to the elder daily activity and safety needs: the so-called Virtual Support Partner (VSP). The VSP is a computer-generated agent represented graphically with a body (for example human or animal) that will play the role of an advisor and assistant helping the elder to carry out daily life activities and thus remain active at home longer.

The care organisations Orbis (Sittard, Netherlands) and MRPS (Geneva, Switzerland) are involved in this project. Their role will be to:

1. Identify the functionalities and services that are relevant for elderly,
2. Ensure that the Miraculous-Life system will be simply to use and useful for elderly.

This project has received funding from the European Union's Seventh Framework Programme for research, technological development and demonstration under grant agreement no 611421. The project started in December 2013 and will last for three years.

PURPOSE OF THE INTERVIEW

The purpose of this interview is to get information about your daily activities and identify your ideas and requirement about the Miraculous-Life system. With this information, we will make an analysis of the user needs. This analysis will be used to develop a first prototype of the Miraculous-Life system.

CONFIDENTIALITY, ANONYMITY AND RIGHTS OF THE PARTICIPANT

The data from the interviews will be analysed anonymously. Your information will be treated as confidential. You are also free to:

1. Decline to participate to the study for any reason,
2. Refuse to answer any individual question,
3. Withdraw the evaluation or the trial at any time without providing a reason.

QUESTIONS ABOUT THE STUDY

If you have any question, please don't hesitate to contact:

Maarten Coolen (unitmanager Hoogstaete), 088.458.66.66, m.coolen@orbisconcern.nl

Donato Cereghetti (psychologist at MRPS), 076.679.86.56, donato.cereghetti@hotmail.com

Your participation to our project is very important for us: thank you for your contribution!

Appendix B Informed consent form

CONSENT FOR USER NEEDS INTERVIEWS PROJECT Miraculous-Life

The Miraculous-Life project is co-funded by the European Commission under the 7th Framework Programme. The main goal is to design and develop technologies to support elderly with their daily activities.

We interview elderly to get information about their daily activities and the thereby preferred support. With this information, we make an analysis of the user needs. This analysis will be used to develop the technology for this project.

The interview shall consist of two different components. The first part of the interview will be individual, with the elderly in their apartment, potentially supported by one of the employees of Orbis/MRPS. The second part of the interview will be filled in by the elderly themselves; however they will be invited together in a small group of elderly and fill in their own list at the same time. If needed, support from some care givers is available at that time.

The data from the interviews will be analysed anonymously. We can also make audio recordings, which will only be used for analysing the data from the interviews.

You already gave us your consent to participate in these interviews. To be careful and complete, we ask your written consent with this form.

To be filled in by the participant

I declare that I have been informed properly about the project Miraculous-Life. I also received an information brochure.
I hereby declare voluntarily to take part in the interviews for Miraculous-Life. I know that the data from this interview will be analysed anonymously and that audio recordings of these interviews are possibly being made.

I hereby keep the right to end my participation at any time, without having to give a reason.

Name participant:

……

Date: ……..

Signature participant: ……..

For any information please contact:
Maarten Coolen (unitmanager Hoogstaete); 088.458.66.66; m.coolen@orbisconcern.nl
Donato Cereghetti (psychologist at MRPS); 076.679.86.56; donato.cereghetti@hotmail.com