Project Identification

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AUTHORSHIP & REVIEWER INFORMATION

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ABBREVIATIONS

ABBREVIATIONS	DESCRIPTION
AAL	Active and Assisted Living
AAL CMU	AAL Central Management Unit
GDPR	General Data Protection Regulation
PwD	Person(s) with Dementia

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EXECUTIVE SUMMARY

This document presents the ethical guidelines and regulations including all ethical procedures of the project as well as the roles and responsibilities of the Ethics Committee. The guidelines instruct the combination of partners' existing ethical protocols and forms, to result in a common SUCCESS Ethics framework which is used as an ethical background to all contact with end-users. Apart from the guidelines, this document includes a sample consent form that will be the basis for the participation of the users to all research activities carried-out in the framework of the SUCCESS project.

1 ABOUT THIS DOCUMENT

1.1 ROLE OF THE DELIVERABLE

The role of the deliverable is to define at the early stage of the project the framework of Ethical Guidelines. The document highlights the Ethics Committee instrument in SUCCESS project and the consent form template that will be used for the evaluation tasks of the project.

1.2 RELATIONSHIP TO OTHER SUCCESS DELIVERABLES

The deliverable is related to the following SUCCESS deliverables:

DELIVERABLE	RELATION
D2.1 Caregiver Require-ments	The methodology of the ethnographic study and the co-design workshop described in D2.1. rest on the present ethical guidelines

2 GENERAL ETHICAL MANAGEMENT METHODOLOGY

In the context of the SUCCESS project, data collection from final users and experts will be carried out in the framework of the following activities:

(1) ethnographic studies including participant observation studies (visits to care homes of PwD) and ethnographic interviews;

(2) expert workshops to validate the evolved insights from (1);

(3) co-creation workshops that will validate the requirements and scenarios result in brain-storms, visualized design ideas, design scenarios and simple prototypes;

(4) evaluations based on feedback from real end users and experts (UX, dementia).

User feedback and evaluations of the prototype will be performed in the lab (Wizard-of-Oz study, informal "friendly user tests", lab study) and the field (qualitative- and quantitative-focused study in a home environment in terms of user experience, acceptance, and health improvement). SUCCESS team will thoroughly investigate the ethical and privacy implications of these activities, especially in the scope of the user involving processes where these privacy issues will arise. In particular, the trial protocol (to be designed) will undergo ethical approval by the involved user sites.

2.1 USER INVOLVEMENT PRINCIPLES

The SUCCESS project will use the 7 principles of FORTUNE for the User Involvement:

Principle 1: Partnership - Co-operation is based on the idea of partnership.

Principle 2: User-Organisation Based - Users are members or representatives of an organisation.

Principle 3: Equal Payment - Users receive payments on the same basis as all other partners.

Principle 4: Accessibility - All project materials, communications and premises are made accessible.

Principle 5: Qualified Staff - Every partner has to provide qualified staff members.

Principle 6: Sound Plan - The project plan contains appropriate WPs and tasks of user participation.

Principle 7: Early Involvement - Users are partners from the very beginning of a project.

Following these guidelines also means that when the field trials are conducted, this will be done in accordance with the highest ethical standards from Europe and the countries where these user studies are to be conducted and Canada. To ensure that the information is easy to understand, all written information that is given to subjects has to be proved by experts on "Easy to Read" guidelines.

All collaboration with end users will be based on an "Informed Consent Form" prepared before the project start. Participants will get information in a way that is easy to understand. There has to be consent for all activities of each single participant to take part in the project. A cancellation of the participation is possible at any point and any time without giving a reason. There will be written information about the usage of all collected data.

Caregivers with reduced capacity to act, i.e. subjects that are not able to exercise independently their individual right to give informed consent will not be recruited in the SUCCESS project.

2.2 MANAGEMENT OF ETHICAL ISSUES AT PROJECT LEVEL

SUCCESS will make a significant effort to fully analyze and take in to consideration all ethical issues that may arise during the lifetime of the project. To ensure the validity of the ethical approach taken in the project, an Ethics Committee will be established, to guarantee that the fundamental ethical principles that research on human beings has to have are met.

The ethical procedures to be established and applied in the project, will firstly be reviewed and approved by an Ethical Committee to be established in the project with the participation of representatives from the end user sites (EUR, RAS) and the coordinating researchers (AIT, UiO). This committee will also include one expert from RAS with lot of experience in ethical issues who will manage the Ethics Committee and ensure objective ethical assessment out of the project´s scope.

The ethics committee is responsible for ensuring that the research performed in SUCCESS conforms to European, national and institutional codes of ethics and legislation. One of the aims of the ethics committee will be to ensure that researchers' interactions with end users are ethical and that best practice ethical management (e.g. request of permissions from relevant authorities, drafting of material necessary for obtaining permissions, drafting of informed consent forms, etc.) has been applied. For this purpose, a task is devoted to supervise the ethical issues during the whole duration of the Project, included in WP1 (see D1.2 Project Handbook).

2.3 POSSIBLE RISKS AND THEIR MANAGEMENT

The risks associated with the participation in the SUCCESS studies are estimated to be low because the content is developed according to evidence-based literature and in consultation with healthcare professionals. A risk associated with the field trials is related to the efficacy of the implemented solution. The nature of the SUCCESS app involves the usage of caregivers. A poor usability and an unattractive architecture or content may discourage caregivers to use the app.

Regarding the problem concerning robustness of services, the mitigation consists in the development of tools (helpdesk, contact persons) that allow a punctual communication with the end user and the enablement of logging to collect information about the correct operation of the system. The participants have the option to contact a local person from AIT/EUR (Austria) respectively RAS (Romania) for support and information. Based on the nature of requests, a phone call or a home appointment will be scheduled to help the participant. In case the local team cannot solve the requests on its own, the technical partners of the SUCCESS consortium will be contacted. To support all users, particularly those who have low familiarity with technology, a SUCCESS training will be provided at the beginning of the study, if necessary.

2.4 NATIONAL ETHICAL COMMITTEE'S APPROVALS

No trial will be performed without previous approval by the ethical committee of the involved countries and data protection authorities of the respective countries. AIT is responsible for coordinating the ethical approvals in Austria, RAS is responsible for coordinating the ethical approvals in Romania. The pilot/field trials are for testing and validation purposes and will respect the following aspects:

- Subjects/patients will be informed volunteers;
- A formal informative consent will be prepared and signed by the subjects/patients;

- The re-examination of data is independent from the presence of the patient/subject;
- Data will be password protected to ensure privacy.

Therefore, the partners involved in the evaluation of the SUCCESS app will receive ethical approval from the National Ethical Committee prior to the beginning of the evaluation phase. To guarantee that there is no delay in the evaluation phase, the partners will submit the request with a large time in advance. As soon as the evaluation protocols are ready the partners will initiate ethical approval procedures.

2.5 HANDLING OF INFORMED CONSENT

During the project informed consent processes will be mandatory. Formal and Informal caregivers participating in the ethnographic study and/or trial of the project will be required to complete an informed consent form in order to be involved in the research activities or to consent to the usage of the SUCCESS app. Hence, SUCCESS will provide an informed consent form and related documentation will be provided to all formal and informal caregivers in their native language to ensure that there is no intimidation involved in their decision to participate. For all users participating in the trial, the informed consent form will describe the trial protocols, along with all ethical implications of the project. The form will be common across all pilot sites, and will be reviewed and approved by the Ethical Committee.

2.6 DATA ANONYMIZATION, ENCODING AND TRANSFER

Data collected from the trials will be treated anonymously in the development of any reporting, and specific feedback from the users will not be identifiable with the originating individuals.

Within SUCCESS we will follow the unlinked anonymized data policy, excluding identifiers, except age, gender and nationality. Once anonymized, the data will not allow tracing back the participant in any way. Data will be encoded, and anonymized using numerical codes. During the trials, the correspondence with the users list will be saved into a local database, which will be encrypted.

2.7 PUBLICATION AND ANALYSIS

The dissemination and publication of the results obtained are one of the primary aims of scientific re-searchers. The publication of the results involves the conflict between privacy interests of the individual participant and the need for free exchange between scientific experts. There are a number of good practice codes and regulations that guide the researcher in handling this conflict. All partners in the project will adhere to the Declaration of Helsinki (World Medical Association - Declaration of Helsinki). For analysis, only data, which are made anonymous, are used and statistical results are only published as summary statistics to prevent the identification of individuals.

2.8 ETHICS DOCUMENTS NEEDED

As illustrated in the previous paragraph, the SUCCESS partners have a sound understanding of the ethical processes needed at national and EU level, as well as of the structure and content of the relevant documents (notably the description of the study and the informed consent forms). As al-

ready outlined the partners will adapt these documents according to the requirements of their respective countries, while they will also provide localized versions of the documents. As an example, we provide in Annex A a sample consent form.

3 ETHICAL GUIDELINES

3.1 GENERAL PRINCIPLES

SUCCESS will be in line with the following guideline, as stated in the Seventh Framework Programme (Decision nª 1982/2006/EC), Article 6: "All the research activities carried out under the Seventh Framework Program shall be carried out in compliance with fundamental ethical principles". SUCCESS, deals with a number of aspects that might impose ethical issues.

The project will carry out user requirements analysis and evaluation involving formal and informal caregivers of persons with dementia (PwD). As PwD can be considered to be a group that is vulnerable, specific attention is to be paid to involving their caregivers in a way that maintains security, privacy and confidentiality of participants and respects the common values of autonomy, independence, beneficence, non-maleficence and justice.

There will be a continuous watch of new laws and legislations that may arise during the project development, regarding the ethical management of research with humans within national and EU levels, to ensure that if new legislations arise during the project, they will be immediately applied to the project's research strategy.

In preparing the ethnographic studies, the expert workshops and the trials, we will guarantee the comfort and safety of participants and/or professionals who take part in them, as well as the security of their personal data acquired during the above mentioned activities. SUCCESS will follow the recommendations of the European group on ethics in science and new technologies to the European Commission. Furthermore, all consortium members agree to adhere to the Helsinki Declaration of 1964 (Recommendation for conduct of clinical research). All national legal and ethical requirements of the Member States where the research is performed will be fulfilled. There will be arrangements for protecting the confidentiality of personal data of participants at any time of the research, as also detailed in following paragraphs. Fundamental safety issues of good laboratory practices will be respected. Potential safety implications of SUCCESS will be clearly indicated.

This means in detail that:

- All the test subjects must give informed written consent to participate.
- All the subjects will be strictly volunteers and are able to withdraw from the trials at any time without any restraints.
- All personal data collected during the ethnographic study, expert workshops and/or trial will be strictly confidential.

In addition, all volunteers, following detailed oral information, will receive in their own language:

- A commonly understandable written description of the project;
- The project objectives;
- The planned project progress;
- The related testing and examination procedures;
- Advice on unrestricted disclaimer rights on their agreement;

- Access to a complaints procedure.

The written information as well as the sought informed consent corresponds to the revised version of the mentioned Declaration of Helsinki. Participants with legal guardian aids, as well as participants who cannot rationalize the expected end-user activities and goal based on any impairment of their cognitive abilities will be excluded from any project study.

At this point, we would like to stress the importance that the SUCCESS Consortium places on the close collaboration between the teams conducting the recruitment of formal and informal caregivers of PwD for the ethnographic study and trials, as well as those teams conducting the actual research. The recruitment of test subjects for the trials will be made on the basis of concrete inclusion/exclusion criteria. The Consortium will pay every effort possible to harmonize these inclusion/exclusion criteria for both trial sites, however, we are aware that there will also be some trial site-specific criteria, given the differentiation of national legislation on these issues.

At all cases, in addition to national legislation, which in many cases is generic and/or inadequate to cover the specific project needs, the SUCCESS Consortium will consult very closely with the experts involved in the recruitment of participant about their ability or not to give informed consent (especially where the caregiver is a partner and can be categorized as an elderly person), since it is these experts who interact and follow the progress of each test subject on an everyday basis and this makes them to most appropriate persons to decide about the cognitive ability or not of a test subject.

Thus, the consortium shall implement the project in full respect of the legal and ethical national requirements and code of practice. Whenever authorizations have to be obtained from national bodies, those authorizations shall be considered as documents relevant to the project. Copies of all relevant authorizations shall be submitted to the Commission prior to commencement of the relevant part of the project.

3.2 GUIDELINES FOR DEVELOPING THE INFORMED CONSENT AND DATA PROTECTION

Informed consent is the process by which a participant will be fully informed about the research in which he/she is going to participate. It originates from the legal and ethical right the participant has to direct what happens to his/her body and personal data and from the ethical duty of the investigator to involve the participant in research. Seeking the consent of an individual to participate in research reflects the right of an individual to self-determination and also his/her fundamental right to be free from bodily interference whether physical or psychological and to protect his/her personal data. These are ethical principles recognized by Law as legal rights. A distinction between three informed consent elements is possible: the information given, the capacity to understand it and the voluntariness of any decision taken.

Respect for persons requires that participants, to the degree they are capable, be given the opportunity to choose what shall or shall not happen to them. This opportunity is provided, when adequate standards for informed consent are satisfied.

The written information as well as the sought informed consent corresponds to information gathered from the revised version of the Helsinki Declaration of 1964, as lastly amended in Tokyo, 2004, and the Convention of the Council of Europe on Human Rights and Biomedicine (1997).

3.2.1 BASIC ELEMENTS OF INFORMED CONSENT

In order to involve a human being as a participant in research, the investigator will obtain the legally effective informed consent of the participant or the participant's legally authorized representative.

All investigators within SUCCESS will seek such consent only under circumstances that provide the prospective participant or the representative sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence.

The information given to the participant or the representative will be in language understandable to the participant or the representative.

No informed consent, whether oral or written, may include any exculpatory language through which the participant or the representative is made to waive or appear to waive any of the participant's legal rights, or releases or appears to release the investigator, the sponsor, the institution or its agents from liability for negligence.

The informed consent will contain a description of the procedures for protecting the confidentiality of personal data.

Much research revolves around information about people – their age, lifestyle, health and work – drawn from records, scientific tests, surveys and interviews. Sometimes, the information also reveals facts about relatives and relationships. These types of information are sensitive and private for many people, although attitudes and expectations vary widely.

The protection of the privacy of participants is a responsibility of all people involved in research with human participants.

Privacy means that the participant can control the access to personal information; he/she decides who has access to the collected data in the future.

Due to the principle of autonomy the participants have to be asked for their agreement (informed consent) before private information can be collected.

It should be also ensured that all the persons involved in the research work, understand and respect the requirement for confidentiality. The participants should be informed about the confidentiality policy that is used in the research.

The privacy plays a role at different levels:

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

Furthermore, the participants have to be able to control the dissemination of the collected data. The investigator is not allowed to circulate information without anonymization. This means that

only relevant attributes, i.e. gender, age, etc. are retained. Another possibility is to keep the identity of the participants, but only with prior consent of those.

While common law establishes some core principles, it does not specify when confidential information may be disclosed to others, in research. Individuals and organizations using confidential information have to take responsibility for deciding what is justified and acceptable on a case-by-case basis (Medical Research Council, 2000).

3.2.2 RESPECT FOR PRIVACY AND CONFIDENTIALITY

In the behavioral sciences, respect for privacy and confidentiality is a central concept in the conduct of ethical research with human participants. Difficulties with privacy issues can lead to difficulties in properly conducting research. If a participant perceives that his or her privacy is threatened this can lead to biased sampling, evasive and/or false responses, and many other impediments that can affect the validity of the results.

As already mentioned, protection of confidentiality implies informing the participants about what may be done with their data (i.e. data sharing). As databases are developed, confidentiality will become increasingly hard to maintain. Simple stripping of the participant's name and its replacement with a code is no guarantee of complete confidentiality.

A question currently under debate among behavioral scientists is whether a consent form stating that personal data will not be shared precludes sharing of data even if identifying characteristics are removed. The removal of identifying information from data gathered on an individual may not be enough since identities can be reconstructed from disparate data sources.

There are solutions to the challenge of maintaining confidentiality including substituting numerical identifiers for names, aggregating data so that the performance of individuals is not obtainable, encryption or layering data so that researchers who need identifying information can obtain it only after signing a legal document that requires honoring the confidentiality of individuals. Researchers who do not need identifying information can have free access to aggregated data.

Visual information will be used as provided (no facial and other features altered) and all accompanying information will be clearly indicated as example/fictional. The possibility of intentionally modifying this accompanying information will be considered for minimizing the chance of user identification by external-to-the-project subjects. This way, legislation restrictions will not pose any obstacle to the project's implementation. In addition, all stored information will be made available only to authorized users through special secure access management mechanisms, therefore, avoiding jeopardizing personal privacy when the project's results will be commercially exploited.

3.3 GUIDELINES FOR DATA ANONYMISATION, ENCODING AND TRANSFER

3.3.1 DESCRIPTION OF THE PROCESS OF ENCODING OR ANONYMIZATION USED

Information should be anonymized so that individual identities cannot be revealed. Anonymization provides a safeguard against accidental or mischievous release of confidential information.

There are different ways in which personal data can be modified to conceal identities:

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

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

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

Researcher and database developer should always consider – when designing studies, before passing information to others, and before publishing information – whether data contain combinations of such information that might lead to identification of individuals or very small groups. How much of this potentially identifying information can be safely included in data that is assumed to be unidentifiable can only be judged on a case-by-case basis taking into account the sample size, the ways in which results will be published and used (Medical Research Council, 2000).

The questionnaires will be handled in the strictest confidence – the results will be entered immediately into a database from where each set of results will be given an automatic number and the personal details omitted. The questionnaires themselves will be kept in a folder, which is kept in a lockable drawer. The questionnaires will be destroyed at the end of the project.

Anonymization will be used to protect the user's identity. The name of the persons and any kind of identification data will appear on the consent forms, of which one copy is kept by the project leader and the other one by the person participating to the experiment. All recordings will then be anonymized by assigning a numerical code to each user (local database), and stored accordingly (e.g. Subject 1, Subject 2, etc.). More details are provided in the following Sections. All data will also be anonymized in internal reports, internal communications and external publications.

3.3.2 PROCEDURES FOR DATA TRANSFER

The personal data will be shared by the consortium members in an anonymous form and the participants will need to be informed about why this has to be done. This information needs to be secured to prevent this information from being available outside the consortium.

Within SUCCESS we will follow the unlinked anonymized data policy, excluding identifiers, except age, gender and nationality. Once anonymized, the data will not allow tracing back the participant in any way. Data will be encoded, and anonymized using numerical codes. During the trials, the correspondence with the users list will be saved into a local database, which will be encrypted.

Because of the decentralized consortium building in the SUCCESS project it can be necessary that personal data will travel across borders of the EU and Canada. As a result, data concerning the citizens of a member state are sometimes processed at other partners. Therefore, regulations on data transfers become necessary and will be implemented and observed in the project. It is stated explicitly that data will be transferred from one partner to another within the consortium only after it was made anonymous. The international laws regarding data protection concerning good data management practices on the part of the entities that process data, called 'data controllers', will be followed during the project. These include the obligation to process data fairly and in a secure manner and to use personal data for explicit and legitimate purposes. National laws also guarantee a series of rights for individuals, such as the right to be informed when personal data have been processed and the reason for this processing, the right to access the data and if necessary, the right to have the data amended or deleted. The member States of the EU were required to bring their national legislation in line with the provisions of the Directive by 24th October 1998. In addition, Directive 2002/58/EC specifically deals with the protection of privacy in telecommunications. This Directive states that Member States must guarantee the confidentiality of communication through national regulations. This means that any unauthorized listening, tapping, storage or other kinds of interception or surveillance is illegal.

4 COMPLIANCE TO RELEVANT NATIONAL AND EU LEGISLATION

With respect to security and privacy associated with citizens' data and participation in the SUCCES platform the project will comply with relevant EU legislation and regulations in the countries where the research will be carried out. Moreover, the proposal conforms to relevant EU legislation such as

- National rules for ethical management
- The Charter of Fundamental Rights of the EU
- Declaration of Helsinki (World Medical Association - Declaration of Helsinki), latest version
- Directive 95/46/EC on the protection of individuals with regard to the processing of personal data and on the free movement of such data
- Directive 2002/58/EC "processing of personal data and the protection of privacy in the electronic communications sector
- Nothing in the proposal stands in conflict with the opinions of the European Group of Advisers on the Ethical Implications of Biotechnology (1991-1997) and the opinions of the European Group on Ethics in Science and New technologies (as from 1998).

4.1 NATIONAL RULES FOR ETHICAL MANAGEMENT

SUCCESS will pay special attention to any ethical rules and regulations, stemming from national laws and directives. Such national directives may require additional targeted ethical interventions for specific pilot sites. SUCCESS will ensure compliance with both EU directives and national directives (at the countries where evaluations will be performed).

4.1.1 ETHICAL REGULATION IN AUSTRIA

AIT stays in close contact with the responsible ethics committee in Austria (Ethikkommission der Stadt Wien) to clarify all requirements for ethical submissions. At the beginning of the SUCCESS project, after AIT submitted the documents for the ethical approval of the ethnographic observation, AIT received the information of the ethics committee that it is not required to receive ethics approval from them in order to conduct the studies in SUCCESS. Furthermore, the ethics committee informed the AIT about their limited capacities to process the request about SUCCESS as they are mainly responsible for studies conducted in the Viennese hospital setting (of the Wiener Krankenanstaltenverbund). Thus, ethical approval for the field trials is not required in Austria. The letter of the ethics committee can be found in Appendix A in German language.

4.1.2 ETHICAL REGULATION IN ROMANIA

According to the Law No. 206/2004, Art. 9 (1) related to the good conduct of scientific research, development, technology and innovation, there are also Institutional Ethics Committees (IEC) who are established in those institutions who are part of the national system of research and innovation and other units who are providing the validation of the results (e.g. universities or hospitals). Their role is the fulfilling of the specific codes and the resolution of various complaints received. They have an independent body status with a consultative role regarding the safeguarding of the rights, safety and the comfort of the participants in the clinical trials. Based on this regulation a IEC was set up for the Romanian Alzheimer Society. The request for ethical approval of the SUCCESS trials was sent in August 2017 and subsequently approved (Appendix B in Romanian language).

4.2 THE CHARTER OF FUNDAMENTAL RIGHTS OF THE EU

The Charter of Fundamental Rights in the course of the respective legal trend dedicates a separate article to the protection of personal data. Article 8 sets out the right to the protection of personal data of an individual and thus the protection of personal data has now an own legal basis apart from the right to respect for an individual's private life and the protection of the human dignity. Art. 8 of the Charter sets out the rules for the legitimate processing of personal data, notably that the processing shall be fair and for pre-specified purposes based on the consent of the data subject or other legitimate basis laid down by law. Reference is furthermore made to two rights of the data subject: the right of access to the data and the right to have it rectified. Finally, Art 8 sets out the need for an independent authority, which shall control the compliance with the data protection rules.

4.3 DECLARATION OF HELSINKI

The Declaration of Helsinki is a set of ethical principles regarding human experimentation developed for the medical community by the World Medical Association (WMA). It is widely regarded as the cornerstone document on human research ethics.

4.4 DIRECTIVE 95/46/EC

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. The Directive lays down a series of rights of the data subject, for instance the patient: These are:

- The right of access to his / her personal data
- The right of erasure, blocking or rectification of the data, which do not comply, with the provisions of the Directive, are incomplete or inaccurate.
- The right to be informed of all relevant details relating to the data processing and the rights granted to him/her
- The right to a judicial remedy for any breach of the above mentioned rights.

All these are applicable to SUCCESS. The first three aforementioned rights may be restricted if this is necessary for reasons relating to the protection of the data subject or the rights and freedoms of others or to prevent a criminal offence or for reasons relating to public security.

Regarding regulation at international level, starting from the OECD guidelines including the "Guidelines on the protection of privacy and trans-border flow of personal data" (1981) and "Guidelines for the security of information systems" (1991/92), the SUCCESS consortium in particular acknowledges heterogeneity in international data protection jurisdiction.

4.5 GDPR

In May 2018 the data protection legal framework will be renovated by EU Regulation 2016/679 – i.e. the General Data Protection Regulation (GDPR). The GDPR was adopted in April 2016 and it will become directly applicable in all EU member States as of 25 May 2018. It repeals Directive 95/46/CE (Data Protection Directive – DPD) and modernizes the EU data protection legal framework. The regulations of the GDPR (informed consent, maintenance of records of processing activities etc.) will be pursued in line with the implementation of the GDPR in the involved organizations (in agreements with the organization's data protection officers).

APPENDIX A LETTER OF THE AUSTRIAN ETHICS COMMITTEE

Magistrat der Stadt Wien
Magistratsabteilung 15 –
Gesundheitsdienst der Stadt Wien
Ethikkommission der Stadt Wien
Thomas-Klestil-Platz 8,
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DVR: 0000191

EK 17-120-VK

Wien, 1. Juni 2017

Projekttitel: SUCCESS – SUccessful Caregiver Communication and Everyday Situation Support in dementia care

Sehr geehrte Frau Zechmann!

Bezugnehmend zu Ihrer Anfrage erlaube ich mir auf den §15a Abs. 3a des Wiener Krankenanstaltengesetzes hinzuweisen.

Demnach vor der Durchführung angewandter medizinischer Forschung und von Pflegeforschungsprojekten und der Anwendung neuer Pflege- und Behandlungskonzepte und neuer Pflege- und Behandlungsmethoden eine Ethikkommission befasst werden kann!
Der Gesetzgeber schafft hierbei eine sogenannte **„KANN-Regelung"**, d.h. Sie können bei uns vorbehaltlich unseres Zuständigkeitsbereiches einreichen, müssen dies aber nicht zwingend tun.

Bedauerlicher Weise muss ich Ihnen mitteilen, dass die Ethikkommission der Stadt Wien derzeit nicht über die nötigen Ressourcen verfügt, um Studien im niedergelassenen Bereich oder in Krankenanstalten außerhalb des Wiener Krankenanstaltenverbundes in unserer Kommission zu behandeln.

Ich hoffe Ihnen mit dieser Information weitergeholfen zu haben und verbleibe

mit freundlichen Grüßen
Reinhard Undeutsch

Geschäftsführer der
Ethikkommission der Stadt Wien
Magistratsabteilung 15 -
Gesundheitsdienst der Stadt Wien
3., Thomas-Klestil-Platz 8
Town Town
Tel.: 01/4000-87523

APPENDIX B LETTER OF THE ROMANIAN ETHICS COMMITTEE

SOCIETATEA ROMÂNĂ ALZHEIMER

Societatea Română Alzheimer
Centrul Memoriei
Centrul pentru depistarea, diagnosticul şi tratarea tulburărilor cognitive
Şos. Berceni nr. 10-12, Bucureşti, sector 4
Tel. 021.334.89.40

CENTRUL MEMORIEI MEMORY CENTER

PROCES VERBAL
NR. 7/1.08/2017

Incheiat astăzi 1.08/2017, în cadrul sedinţei Comisiei de Etică a Societăţii Române Alzheimer. Comisia a fost completă, toţi membrii ei fiind prezenţi.

S-au analizat documentele depuse pentru aprobarea studiului etnografic din cadrul proiectului AAL2016, SUCCESS, investigator: Raluca Sfetcu.

Comisia consideră că desfăşurarea studiului mai sus menţionat respectă condiţiile de siguranţă pentru pacient şi principiile de etică pentru cercetare.

Comisia de Etică aprobă desfăşurarea studiului în cadrul Centrului Memoriei, centru pentru depistarea, diagnosticul şi tratarea tulburărilor cognitive aparţinând Societăţii Române Alzheimer.

Aprobarea este valabilă începând cu data prezentei decizii până la data de 31 decembrie 2017.

La încheierea cercetării, investigatorul va trimite un scurt raport astfel încât Comisia de Etică a Societăţii Române Alzheimer să închidă acest dosar.

Supravegeherea problemelor etice ale studiului rămâne în responsabilitatea investigatorului.

Numărul acestei aprobări a Comisiei de Etică va fi menţionat în corespondenţa legată de studiu.

COMISIE ETICA: **Asistent Univ. Dr. Elena –Alina Roşca**
Asistent Univ. Drd. Ana Giurgiuca
Drd. Ioana Caciulă

SOCIETATEA ALZHEIMER ROMANIA