D1.6 Ethics and data manual

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v3.0	06-02-2019	Cheyenne Schuit	NFE	Last check with project leader Stefan Schürz.

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1 Introduction

1.1 The SALSA project

Aim of the AAL Consortium in the SALSA project is to develop a smart-app-based-solution that supports older adults (55+) in starting and maintaining an active lifestyle with or without the supervision of a physiotherapist. Physical activity is known to improve many of the factors associated with ageing and helps older adults to maintain their well-being, functional ability and independence. However, maintaining an active lifestyle or recovering from injury/illness is a challenge where motivation is a key factor. In the SALSA project the aim is to develop a platform that supports seniors to become or remain active by co-creating this with seniors and other stakeholders.

1.2 Scope of this deliverable

The current document therefore describes the moral, legal and ethical aspects that we need to take into account within the context of the SALSA project, both during the development phase as well as afterwards, when the developed tool will be used in practice. For the SALSA project this applies to tasks T2.4 User-centered service model design, T4.1 User testing on pre-prototypes, T4.2 Real-life evaluation protocol, T5.1 Service model design set up and T5.2 Business model design. All insights on moral, legal and ethical aspects are summarized in a directive. This directive for example contains guidelines on how to consider the European legislation GDPR operative from May 2018, with regards to privacy issues and how the different partners can apply this.

Moreover, if applicable state regulations from the countries involved in this project are considered. In particular the partners in the Netherlands, Austria and Switzerland that work with older end users in validation activities. This document is set-up as dynamic document. It contains a manual/guideline and will be complemented with new input during the project.

1.3 Table of content

The document contains the following sections:

- **Chapter 2** includes a general introduction of legislation in Europe, including national legislation in the Netherlands, Austria and Switzerland concerning data processing.
- **Chapter 3** includes information on ethical principles
- **Chapter 4** provides a practical implementation of the chapters above by providing an Ethics Code of Conduct of Research of SALSA
- **Chapter 5** lists the references
- **Chapter 6** shows the informed consents used so far

1 Legislation

1.1 General Data Protection Regulation

1.3.1 Processing data of individual citizens

Since May 25 2018, the General Data Protection Regulation (GDPR) is **operative for all individuals within the European Union**. The GDPR aims primarily to give control to citizens over their personal data and to simplify the regulatory environment for international businesses by unifying the regulation within the EU1 . Under the GDPR, personal data is defined as any information that could be used, on its own or in conjunction with other data, to identify an individual. This data includes IP addresses, mobile device identifiers, and geolocation and biometric data (fingerprints, retina scans, etc.). The GDPR also covers data related to an individual's physical, psychological, genetic, mental, economic, cultural, or social identity.

Superseding the Data Protection Directive 95/46/EC, the regulation contains provisions and requirements pertaining to the processing of personally identifiable information of individuals (formally called data subjects) inside the European Union, and applies to all enterprises, regardless of location, that are doing business with the European Economic Area.

Business processes that handle personal data must be built with data protection by design and by default, meaning that personal data must be stored anonymized. Furthermore, the highest-possible privacy settings should be built by default, so that the data is not available publicly without explicit consent and cannot be used to identify a subject without additional information stored separately. No personal data may be processed unless it is done under a lawful basis specified by the regulation, or if the data controller or processor has received explicit, opt-in consent from the data subject. The data subject has the right to revoke this permission at any time.

A processor of personal data must clearly disclose any data collection, declare the lawful basis and purpose for data processing, how long data is being retained, and if it is being shared with any third-parties or outside of the EU. Data subjects have the right to request a portable copy of the data collected by a processor in a common format, and the right to have their data erased under certain circumstances.

1.3.2 Special categories of data processing

The GDPR creates more restrictive rules for the processing data relating to race, religion, sexual life, data pertaining to health, genetics, biometrics and personal data relating to criminal convictions and offences. It is concerned with the "**processing**" of personal data, which means any set of operations performed on data, including the mere storage, hosting, consultation or deletion of the data. In contrast to the previous law, the GDPR imposes direct obligations on both the controller (the decision maker) and the processor (who processes personal data on behalf of the controller), although fewer obligations are imposed on the processor. As SALSA also focusses on seniors with health problems, these rules on data processing could apply to SALSA.

Art. 7 prescribes conditions for demonstration of such a consent. When consent is given in a written form, it should be clearly distinguishable from the rest of the information provided to the data subject. The informed consent shall leave no possible space for ambiguity or confusion for the data subject and it should make clear that the aim is to collect and process their personal data. The consent should use clear and plain language, which means that its content shall not be hidden behind complex legal formulas. It is necessary to inform the data subject of the possibility to withdraw their consent at all times and without need of any uneasy procedures. The withdrawal of consent shall however not affect

the lawfulness of processing of data based on consent given before its withdrawal; and the data subject shall be informed thereof.

Before personal data are collected from the data subject, data controller shall provide him/her with a variety of information prescribed in Art. 13 and 14, such as the identity of the controller, contact details, the purpose of the processing of data (lawful processing), the period for which data is going to be stored, the existence of the right to request from the controller access to and rectification or erasure of personal data, the right to lodge a complaint with a supervisory authority etc.

GDPR further acknowledges a range of rights for data subjects whilst the existence of these rights should be brought to the attention of the data subject in the explicit and clear manner in the informed consent. These rights include among other the following [Art 15-22]:

- The right to information (requirement of transparency)
- Right to access, erasure, rectify or restrict data
- Right to data portability to other data controller – this is a right to receive the personal data concerning the data subject, which he or she has provided to a controller, in a structured, commonly used and machine-readable format and have the right to transmit those data to another controller
- Right to object against further processing

1.3.3 Data protection officers

Articles 37-39 refer to the appointment of a data protection and describe in which circumstances the appointment of such an officer is recommended and necessary. Appointment of DPO is necessary if data are processed by a public authority or if the core activities consist of processing operations which require regular and systematic monitoring of data subjects on a large scale; or the core activities consist of processing on a large scale of special categories of data, health data included.

Data protection officer (DPO) will need to be a person with sufficient level of expert knowledge. He/she may be a staff member of the controller or processor, or fulfil the tasks on the basis of a service contract.

DPO shall exercise his/her duties independently and in confidentiality. Data subjects may contact the data protection officer with regard to all issues related to processing of their personal data. DPO shall inform and advice the data controller, monitor compliance with GDPR and serve as s contact point for the supervising authority. Below you can find a list of DPO officers of partners in the piloting countries.

Organisation	DPO
NFE	Han Schoonderbeek
LFTL	Markus Becker
TERZ	Stefan Kroll
RRD	Jos Spoelstra

1.3.4 Records of processing activities

In case an enterprise or organization employs more than 250 persons records of processing activities must be kept by each controller as stated by Art 30 of the GDPR. This is also the case for organizations with fewer persons when there is a risk to the rights and freedoms of data subjects, when the processing is not occasional, or the processing includes special categories of data such as to race, religion, sexual life, data pertaining to health, genetics, biometrics and personal data relating to criminal convictions and offences. As SALSA also focusses on seniors with health problems the

consortium must be aware of these rules and be careful how this data is processed. This record contains:

- the name and contact details of the controller and, where applicable, the joint controller, the controller's representative and the data protection officer;
- the purposes of the processing;
- a description of the categories of data subjects and of the categories of personal data;
- the categories of recipients to whom the personal data have been or will be disclosed including recipients in third countries or international organizations;
- where applicable, transfers of personal data to a third country or an international organization, including the identification of that third country or international organization and, in the case of transfers referred to in the second subparagraph of Article 49, the documentation of suitable safeguards;
- where possible, the envisaged time limits for erasure of the different categories of data;
- where possible, a general description of the technical and organizational security measures referred to in Article 32.

Next to this the processes (who process data on behalf of the controller) maintains a record that contains:

- the name and contact details of the processor or processors and of each controller on behalf of which the processor is acting, and, where applicable, of the controller's or the processor's representative, and the data protection officer;
- the categories of processing carried out on behalf of each controller;
- where applicable, transfers of personal data to a third country or an international organization, including the identification of that third country or international organization and, in the case of transfers referred to in the second subparagraph of Article 49, the documentation of suitable safeguards;
- where possible, a general description of the technical and organizational security measures referred to in Article 32.

1.3.5 Data protection impact assessments

For specified types of processing a DPIA need to be performed to help identify and minimise data protection risks of a project, when processing data can result in a high risk to individuals. To find out if there is a high risk to individuals there are checklists. In case of high risks to individuals the DPIA must:

- describe the nature, scope, context and purposes of the processing
- assess necessity, proportionality and compliance measures;
- identify and assess risks to individuals; and
- identify any additional measures to mitigate those risks.

1.4 Data protection in Austria

1.4.1 National data protection law

The Austrian data protection act (Datenschutzgesetz, short DSG) supplements the Data Protection Regulation (GDPR). In summer 2017 the existing Data Protection Act 2000 was amended by the Data Protection Amendment Act 2018. In addition to the GDPR, the DSG is now the central piece of legislation in Austria regulating data privacy. As concerns the territorial scope of application, the relevant provisions of the previous DSG 2000 have not been amended yet and apply under the DSG as well. Thus, the DSG does not apply to data that is processed in Austria where the controller is elsewhere in the EU or where data is only transmitted through Austrian territory. In this case the law of the state applies where the controller is based.

1.4.2 Personal and Sensitive Personal Data

The DSG describes *personal data* as information about an identified or identifiable person. 'Identifiable' means that a name, identification number, phone number, location data or other factors which may identify that natural person, such as IP addresses, cookies and RFID tags will already suffice as 'identifiable' as well.

The Austrian Data Protection Authority is the national supervisory authority for data protection in the republic of Austria. Under the GDPR data controllers no longer need to report the structure (not the actual content) of their data applications to the Data Processing Register (Datenverarbeitungsregister). This is replaced with the records of processing activities (Art. 30 GDPR) and data protection impact assessments (Art. 35 and 36) of the GDPR, which are explained above.

1.5 Data protection in the Netherlands

In the Netherlands the Dutch Data Protection Authority (DPA or autoriteit persoonsgegevens) watches if organization suffice to law and regulation on processing personal information. The GDPR has replaced the 'Wet bescherming persoonsgegevens' (Wbp). The UAVG supplements the GDPR. The UAVG applies if the controller or processor is situated in the Netherlands, or when products or services are offered in the Netherlands or when behavior of individuals is monitored and the behavior takes place in the Netherlands. In case data is processed internationally, it is possible that two different laws are applicable. Based on the UAVG fines can be given when data is not processed accordingly.

1.6 Data protection in the Switzerland

In Switzerland the processing of personal data is mainly regulated by the Federal Act on Data Protection of June 19, 1992 (DPA) and its ordinances, *ie*, the Ordinance to the Federal Act on Data Protection (DPO) and the Ordinance on Data Protection Certification (ODPC). This DPA is most likely to be revised to strengthen data protection in general and to align the DPA with the requirements of the EU General Data Protection Regulation (GDPR), in order to facilitate compliance of Swiss companies with those aspects of the GDPR that are applicable to controllers or processors outside of the EU, and to ensure that the EU will continue to consider Switzerland as providing an adequate level of data protection. As SALSA is an international project we recommend for the Swiss partners to suffice to the GDPR as well.

Authorities:

- Eidgenössischer Datenschutz- und Öffentlichkeitsbeauftragter (responsible for all issues regarding data security)
- Kantonale or eidgenössische Ethikkommission (competence depending on regional scope; must be informed and / or asked to state their opinion in cases in which sensitive medical data of identifiable testing persons shall be handed over to third persons)

Main regulations:

- Bundesverfassung, Art. 13 (Protection of privacy, including the protection of private and family life, home, mail and telecommunication, financial secrecy)
- Bundesgesetz über den Datenschutz (revised January 1, 2014)
- Verordnung zum Bundesgesetz über den Datenschutz (revised December 1, 2010)
- Schweizerisches Zivilgesetzbuch, Art. 28-28l
- Bundesgesetz über die Forschung am Menschen (Humanforschungsgesetz, HFG, revised January 1, 2014)

2 Ethical Principles

2.1 Set of ethical principles

The British Sociological Association (2002) developed a set of ethical principles. Because of its detailed presentation, the integrity of the association as well as of the mentioned sources and references the "Statement of Ethical Practice for the British Sociological Association" acts as basis to get a deeper insight into the topic.

Its ethical principles contain 61 statements in following categories:

- (Introduction: 4 general statements concerning the present guidelines)
- Professional integrity
- Relations with and Responsibilities towards Research Participants
- Relationships with Research Participants
- Covert Research
- Anonymity, Privacy and Confidentiality
- Relations with & Responsibilities towards Sponsors and/or Funders
- Clarifying Obligations, Roles and Rights
- Pre-empting Outcomes and Negotiations about Research

The categories by themselves give a good picture about the issues a code of conduct for research should deal with. They can be seen as framework in which ethical principles should fit in.

Bill Dutton (2010) broke down the 61 statements mentioned above and summarized the key principles in "Six principles to guide research ethics in the social science" that need to be applied in social research:

1. Research should be designed, reviewed and undertaken to ensure integrity, quality and transparency.
2. Research staff and participants must normally be informed fully about the purpose, methods and intended possible uses of the research, what their participation in the research entails and what risks, if any, are involved. The confidentiality of information supplied by research participants and the anonymity of respondents must be respected.
3. Research participants must take part voluntarily, free from any coercion.
4. Harm to research participants must be avoided in all instances.
5. The independence of research must be clear and any conflicts of interest or partiality must be explicit.

Additionally, besides of the content-related statements concerning concrete recommendations/ advices of the ethics principles of the British Sociological Association, two basic messages are presented ibidem. They should be taken into account when developing ethics guidelines and in the accompaniment of the research phases:

1. Ethics in research concerns equally researchers and the participants; both roles must be protected.
2. Ethics guidelines doesn't provide recipes for resolving ethical dilemmas, but makes aware and recognises that it is necessary to make made on the basis of values and interests.

As the amount of literature concerning ethics in social research is very little in comparison with the found literature about ethics in medical trials, it seems to be useful to confront ethics in the field of social sciences with ethics in medical/clinical research. The aims are on one hand to show how similar ethics of different disciplines could be and on the other hand – by its similarity – it underpins the above listed key principles and categories.

2.2 Declaration of Helsinki

"The Declaration of Helsinki – World Medical Association Declaration of Helsinki" is developed for the field of medical research – as the subtitle reveals. The declaration is one of the most common papers that describes shortly ethical principles on an international level and is almost always used as (part of) ethical guidelines in medical studies. Even though we do not do a medical study, SALSA is aimed on seniors with specific health problems. That is why the declaration of Helsinki is mentioned as well.

Abstaining from the medical topic, a bundle of mentioned ethical aspects are very similar and also relevant for social research as human beings are involved as researchers and as participants.

Following ethical aspects of the declaration can be transferred to social research (cf. WHO, 2001):

- The ethical principles provide guidance to the researcher and the participants.
- The ethical standards should promote respect for human beings and protect their health and rights.
- Researchers should protect life, health, privacy and dignity of the participants.

- The researcher shall act only in the participant's interest.
- The well-being of the participant should take precedence over the interests of science and society.
- The participants must be volunteers and adequately informed, especially about potential risks, anticipated benefits and possible conflicts of interest.
- The participant's integrity must be respected.
- The privacy of the participant must be respected.
- Patient's information and data must be handled confidentially.
- Participants must be informed to have the right to withdraw from the participation on the study or to withdraw at any time without reprisal. After ensuring that the participant understood the information the researcher should obtain the freely-given informed consent, preferable in writing.
- Vulnerable populations require special protection. In the case the participant is legally incompetent, physically or mentally incapable of giving consent or is a legally incompetent minor, the legally authorized representative needs to be involved and give the informed consent (with accordance to the applicable law).
- Research with persons' involvement needs to take generally accepted scientific principles of science into account and should be performed only be scientifically qualified persons.
- Researchers should abstain from engaging in research involving persons unless they are confident with the risks that are adequately assessed and can be satisfactorily managed.
- The design of research with participants' involvement should be clearly formulated and documented. The document must be reviewed in regard to ethical aspects.
- Authors and publishers have ethical obligations. Researchers are obliged to preserve the accuracy of the results; negative as well as positive results should be published.
- The ethical board/ reviewer should be in conformity with laws and regulations of the country in which the social research is performed.

How all these requirements could be met and will not be lost from sight in practice? - For projects a tailor-made ethics code of conduct that includes ethical values as well as legal issues must be developed before research activities are done:

The code of conduct serves a common understanding and therefore its rules need to be agreed on by all researchers who have to deal with it (please see the Ethics Code of Conduct of Research of SALSA below). This is especially important for cross-national research, when laws, declarations and standards differ. But not only because of ethical aspects it is so important, also in the sense of scientific work with valid results: only in the case the researchers and the participants in all participating countries have the same level of information and feel comfortable with the research action data will be valid and comparable. The Code of Conduct in cross-national research protects the professional integrity of the researchers, their employers and the scientific community as well as the participants and the social community (see Freed-Taylor, 1994).

Further, Deborah Smith (2003) published the American Psychological Association's strategies for steering clear of ethical dilemmas that can be useful as first advisor also in social research:

1. Discuss intellectual property frankly
2. Be conscious of multiple roles
3. Follow informed-consent rules
4. Respect confidentiality and privacy
5. Tap into ethics resources

2.3 Relation with participants

Within SALSA we may work with older people who may be frail. It is important to take this into consideration. Friendliness, service quality and consulting authority are important. The following criteria should be particularly noted:

- Older people are sensitive to politeness, obligingness and assistance.
- Older people are especially timely; they usually come in time, often even earlier than agreed, so punctuality is important. They are willing to wait a little, but it must not take too long.
- Older people are pleased with little surprises; small gestures for purchases and gifts are almost always accepted with joy. Personal good wishes on special occasions are very well received and long-time regular customers are pleased with Bonuses.
- Older people are less confident; many have fears to be overreached or not to be well versed with technology and electronics. Moreover, they fear to buy something wrong or to receive no service afterwards. Therefore, they like sellers who they know and who they trust.
- Older humans need acknowledgment and appreciation; they want to be taken seriously and importantly.
- Older humans are grateful; that leads to customer connection and to far recommendation. Many older humans continue to tell their purchase experiences to others.

For the research activities, it will be important to treat the research participants according to well-accepted principles, which seem obvious but are often forgotten.

- Give Clear instructions in simple, short sentences.
- A caring, but also specific and clear, tone should be used.
- Repeat important information when needed several times.
- Let them always finish their sentences.
- Take them serious.
- Make sure that they understand everything what you tell them (no foreign words).
- Speak loud and clearly.
- Write complicated procedures down.
- Always maintain eye contact

3 Ethics Code of Conduct of Research of SALSA

Introduction

1. The present *Ethics Code of Conduct of Research of* SALSA doesn't offer a recipe in all ethical belongings but is pointing the way how to come along with ethical dilemmas researchers might be confronted during the project and especially when participant-involvement is addressed during the preparation-, conduction- and evaluation-phase of studies - in SALSA users' data will be processed in five tasks: T2.4 User centred service model design, T4.1 User testing on pre-prototypes, T4.2 Real-life evaluation protocol, T5.1 Service model design set up and T5.2 Business model design.

2. Laws and legal standards (see 2 Legislation) can be seen as basis for all ethical aspects that must be taken into account by the SALSA-project members.

3. The Ethics and Data manager (EDM) assigned by NFE ensures that ethical and privacy issues are properly addressed throughout all project activities.

4. Every member of the consortium has to be compliant to the present Code of Conduct and - in support of the ethical supervisor - responsible for its fulfilment.

5. Every conducting researcher of the tasks T2.4 User centred service model design, T4.1 User testing on pre-prototypes, T4.2 Real-life evaluation protocol, T5.1 Service model design set up and T5.2 Business model design is responsible for the observation in regard to ethical and legal aspects and the fulfilment of the Code of Conduct as part of his daily work.

6. In the case one or more than one researcher doesn't feel confident and assume an ethical or legal dilemma he/ they has/ have to report the doubts to the EDM. In the case neither the EDM nor the consortium can disperse or solve an ethical or legal dilemma satisfactorily the ethics committee/ board of the country where the dilemma arose has to be consulted.

7. Other responsibilities in the project, the ownership of results, access rights for implementation and for dissemination and exploitation activities as well as the Intellectual Property Rights are regulated in the Consortium Agreement and therefore are not objects of the present Ethics Code of Conduct.

Researchers

8. Researchers commit themselves to observe and to promote the principles of scientific integrity. These include (ESF, ALLEA, 2011: 8):

    a. Honesty in reporting and communicating

    b. Reliability in performing research

    c. Objectivity

    d. Impartiality

    e. Independence

    f. Openness

    g. Accessibility

    h. Duty of care

    i. Fairness in providing references and giving credits

j. Responsibility for the future science generations.

9. The researcher is responsible for the integrity, quality, conscientiousness and transparency of research.

10. The researcher must be appropriately informed about the project, funding, aim of the research, methods and his duties.

11. In the case the researcher doesn't feel confident with the available information he is responsible to gain his knowledge and to involve the task leader and/ or the project leader.

12. The researcher is responsible for the wellbeing of the participant and must protect his rights, interests, sensitivities and privacy. Further he must respect his anonymity.

13. The relationship between the researcher and the participant must be trustful and morally.

14. Researchers must not be constrained to reach particular conclusions or to make any recommendations – neither by members of the consortium, the scientific community or funders nor by one or more participants or society. In such a case the project leader and the ethics supervisor have to be informed promptly.

15. The researcher as well as the consortium has to guarantee safety of the participants. The credit of persons who want to be registered at the SALSA-platform and who are able to exchange services and meet others in real life must be proven previously. Therefore, the consortium must develop concrete measures.

16. In the case of an ethical dilemma of the researcher the ethics supervisor has to be involved (see also 6.1 Introduction).

Participants

17. The participant must take part voluntarily and free from any coercion.

18. The participant's confidence as well as his wellbeing during the involvement must be the prior and highest good for the researcher and the consortium.

19. The project consortium and especially the researchers on-site have the responsibility to the physical, social and psychological wellbeing of the participant and that it is not adversely affected by the research.

20. Vulnerable persons must be protected especially. Special care should be taken in case the participant is legally incompetent, physically or mentally incapable of giving consent or is a legally incompetent minor. In that case caregivers, legal representatives and the participant's general practitioner could be included in the process of giving informed consent.

Informed Consent

(The Informed Consents that are developed for SALSA are attached to the present deliverable - see Appendix)

21. The informed consent must be written in the language of the country where the research activity will be conducted. Therefore, the Informed Consent of the Netherlands must be written in Dutch and the Informed Consent of Austria in German.

22. At the very beginning of each end user involvement every participant must be informed by the researcher about the project, the aim of research, the methods and - if requested by the participant – also about other information concerning the research and the project (e.g. funder) that is not confident.

23. The researcher has the responsibility to make sure that the participant understood the given information about the project, the aim of research, the methods and - if requested – also about other information concerning the research and the project.

24. The researcher has to obtain an informed consent in written form, confirmed by the participant by signature. Therefor the informed consent must contain:

    a. Signature of Participant

    b. Date

25. The informed consents must contain following information at minimum:

    a. Personal details and given statements will be treated in strict confidence and will be processed in an anonymous form.

    b. In the case the participant doesn't feel comfortable to answer a question he has the possibility to reject the question.

    c. At any point during the involvement the participant has the possibility to terminate the research activity.

    d. The decision of rejecting a question as well as to terminate the research activity will not have any consequences for the participant.

26. In the case the participants must be registered at the SALSA platform and use it in the sense of SALSA (e.g. in later prototype tests and the pilot) the Informed Consent that must be signed by the participant before his registration at the platform must contain additionally:

    a. Who has access to the data shown at the platform (e.g. team of researchers, technical project partners, other users).

    b. In which way the data presented at the platform will be used.

    c. Who will process the data presented at the platform (e.g. team of researchers, technical project partners).

    d. What is the aim of using the data presented at the platform.

    e. What are the expected positive aspects for the participant to use the platform.

27. In iterative phases of T2.4 User centred service model design. T4.1 User testing on pre-prototypes and T5.1 Service model design set up, the researcher must obtain a signed Informed Consent (in written form) at every point of the phase when the participant has to answer questionnaires or will be contacted for interviews. The given Informed Consent must not be seen as a once-for-all-prior event. For the Informed Consents of the iterative phase the above mentioned paragraphs must be considered.

28. Even if one or more "gatekeepers" are involved for reaching one or more participants the Informed Consent must be obtained from the participant by the researcher directly, while at the same time the interests of the "gatekeeper(s)" must be taken into account.

29. The participant must receive a copy or duplicate of the Informed Consent. It should additionally contain contact details of the researcher for questions/ queries that could come up later.

Data

30. Data will be generated only in an anonymized form. Therefore, the questionnaires, interview guidelines and other used instruments must not contain questions, which answers could lead to the participant's identity – alone or in combination with other answers.

31. The anonymity and privacy of participants must be respected. Personal information must be kept confidential. Guarantees of confidentiality and anonymity given to the participants must be honored, unless there are clear and overriding reasons to do otherwise.

32. In the case the participants must be registered at the SALSA platform and use it in the sense of SALSA (e.g. in later prototype tests and the pilot) they can register with their name, if they choose so themselves. This can make it easier for participants to find other group members. However if we want to use related data of how they use the platform for research purposes, this name must be coded in our research, so that answers cannot be traced back to the individual. E.g. an ID-code will be applicable instead of it in our research documents. That guarantees the anonymity of the participant and further, the ID-code helps to match answers of questionnaires and the data presented at the platform by the user.

33. The participants themselves have their data sovereignty. In the case the participant wants the deletion of his data this has to be done promptly. But because of the anonymization data can only be deleted during or immediately after the end user involvement.

34. The participant is allowed to change/ limit the access authorization of his data presented at the SALSA-platform.

35. It is strongly recommended to add the rules 33., 34. and 35. to the informed consents.

36. Only information pertinent to the research is permitted to be collected.

37. All researchers have the duty of confidence in regard to collected data.

38. The integrity of processed and published data must be ensured by the researchers and the project consortium. E.g. for the purpose of proofing tasks of the SALSA partners, the national funding agencies of the countries where the research will be conducted and also the European Commission as funder data can be hand out in original form (e.g. filled out questionnaires). They are the only institutions with this special right.

39. The limitation of two years in paragraph 08. Non-Disclosure of Information/ Confidentiality/ Privacy of the Consortium Agreement in regard to the preserving the confidentiality of any data isn't in force for personal data of end users involved in the social research.

40. Data that are presented by the participant at the platform must be treated with care:

    a. Participants must be informed that the data could be used for the project

    b. Participants must be informed in which way the data could be used (see also 6.2 Informed Consent).

    c. The participants must be informed who has the data sovereignty (see also 6.2 Informed Consent).

    d. The participants must be informed if the presented data will be deleted in the end of the project.

    e. The project consortium is responsible for the risk management: to avoid participant's inconveniences, damage of the personal integrity of the participant and the researcher appropriate measures must be taken.

f. Appropriate measures must be taken to protect the presented data by the technical partners and the consortium.

g. Appropriate measures must be taken to store data in secure manner.

h. In the case the participant withdraws from the test/ pilot the presented data at the platform must be deleted or the access to them must be impossible for others?

i. Every access to the data must be protocolled. Every registration must contain the name of the researcher who had access, his signature, the date and the description of accessed data. Every partner who has access to the data must keep the minutes.

j. Care professionals could have access to data that could be helpful for their offers. Therefor the participant must agree in the informed consent.

4 References

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5 Appendix

5.1 Informed Consents – EN

Invitation letter research: [subject]

Dear Sir / Madam,

Hereby we would like to invite you to participate in a study. [Your organisation] is participating in a research project called SALSA, in which a new technology is being developed to support people of 55 years and older in an active lifestyle.

We would like to development this technology and the application in daily life in collaboration with the users. This includes people of 55+, physiotherapists, (sport)trainers and initiators who organise sport activities in groups. As a first step, we would therefore like to talk to you.

Aim of the study: [place in your study, e.g.:] With this study we want to gain insight into how people aged 55 and over view healthy living and exercise: what are they already doing in this area, what problems do they encounter and where more support is needed?

The investigation: [what does this research activity entail? E.g.:] The investigation consists of a one-hour interview. In this interview you first complete two short questionnaires about yourself. Then the Interview starts. Herein we ask about any health complaints you have, how these complaints arise and how this affects the performance of physical activities.

Audio recordings are made during the interview. These audio recordings are stored as protected files and will only be used by us to listen back to what is said. We then destroy these recordings. All data is treated confidentially and stored anonymously. You can stop participating in the study at any time without giving a reason.

We hope that you want to participate in this study. If you are interested in participating or have questions about the research, you can contact [name of person]. You will find the contact details below.

[your name]

[position]

[organisation]

[email]

[telephone]

[working days]

Permission form

Title of the study: [Title of research activity]
Name of the project: SALSA

☐ Yes, I would like to participate in this study.

Name:

Mail:

Phone number:

Address:

Residence:

I hereby declare that I am well informed about the goals and method of this study. All my questions have been answered and I have had sufficient time to make a good decision about my participation.

My choice to participate in this study is entirely voluntary. I have the right to stop participating at any time without giving a reason.

I authorize the use of my data for the purposes of the journal study. I agree that the following data will be collected:

• Demographic data, such as age, gender and living situation

• Audio recordings of the introduction and evaluation interview

• Questionnaires about healthy living and how you view your health

• Information about the origin and course of health problems

• Information about physical activities

The results of this study may be used for scientific publications and presentations and will be stored anonymously in the electronic records of [Name of company and place], [country].

Date: Signature participant:

Date: Researcher's signature:

5.2 Informed Consents - NL

Uitnodigingsbrief onderzoek: Interview over de gezondheid van ouderen (55+)

Beste Meneer, Mevrouw,

Hierbij willen we u graag uitnodigen voor deelname aan een onderzoek. Het Nationaal Ouderen Fonds werkt samen met Roessingh Research and Development aan een onderzoeksproject, genaamd SALSA, waarin een nieuwe technologie wordt ontwikkeld om mensen van 55 jaar en ouder te ondersteunen in een actieve leefstijl.

De ontwikkeling van de technologie en de toepassing in het dagelijks leven willen we graag in samenwerking met de gebruikers (mensen van 55 jaar en ouder) doen. Als eerste stap willen we daarom graag met u in gesprek.

***Doel van het onderzoek*:** Met dit onderzoek willen we inzicht krijgen in hoe mensen van 55 jaar en ouder tegen gezond leven en beweging aankijken: wat doen ze al op dit gebied, tegen welke problemen lopen ze aan en waar is meer ondersteuning nodig?

Het onderzoek: Het onderzoek bestaat uit een interview van een uur. In dit interview vult u eerst twee korte vragenlijsten over u zelf in. Daarna begint het Interview. Hierin vragen we naar eventuele gezondheidsklachten die u heeft, hoe deze klachten ontstaan en hoe dit invloed heeft op het doen van fysieke activiteiten.

Tijdens het interview worden audio-opnames gemaakt. Deze audio-opnames worden als beveiligd bestanden opgeslagen en zullen we alleen zelf gebruiken om later nog eens terug te luisteren wat er gezegd werd. Daarna vernietigen we deze opnames. Alle gegevens worden vertrouwelijk behandeld en anoniem opgeslagen. U kunt te allen tijde, zonder opgaaf van reden stoppen met deelname aan het onderzoek.

We hopen dat u mee wilt doen aan dit onderzoek. Als u geïnteresseerd bent in deelname of vragen hebt over het onderzoek, kunt u contact op nemen met Marijke Broekhuis, onderzoeker bij Roessingh Research and Development. De contactgegevens vindt u hieronder.

Marijke Broekhuis
Onderzoeker
Roessingh Research and Development

Cheyenne Schuit
Functie
Nationaal Ouderen Fonds

Mail: m.broekhuis@rrd.nl
Telefoon : 088 087 5728
Werkdagen : ma-vrij

Toestemmingsformulier

Titel van het onderzoek: **Interview over gezond leven**
Naam van het project: SALSA

☐ Ja, ik wil graag deelnemen aan deze studie.

Naam :
Mail :
Telefoonnummer :
Adres :
Woonplaats :

Ik verklaar hierbij dat ik goed geïnformeerd ben over de doelen en de methode van deze studie. Al mijn vragen zijn beantwoord en ik heb voldoende tijd gekregen om een goede beslissing te maken over mijn deelname.

Mijn keuze om deel te nemen aan deze studie is geheel vrijwillig. Ik heb het recht om op elk moment te stoppen met mijn deelname, zonder een reden op te hoeven geven.

Ik geef toestemming voor het gebruik van mijn data voor de doelen van de dagboekstudie. Ik ga ermee akkoord dat de volgende data verzameld wordt:

- Demografische gegevens, zoals leeftijd, geslacht en woonsituatie
- Audio-opnames van het introductie-en evaluatiegesprek
- Vragenlijsten over gezond leven en hoe u tegen uw gezondheid aankijkt
- Informatie over het ontstaan en verloop van gezondheidsklachten
- Informatie over fysieke activiteiten

De resultaten van deze studie mogen gebruikt worden voor wetenschappelijke publicaties en presentaties en zullen anoniem opgeslagen worden in de elektronische administratie van Roessingh Research and Development in Enschede, Nederland.

Datum : Handtekening deelnemer :

Datum : Handtekening onderzoeker :