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[1] L = Legal agreement, O = Other, P = Plan, PR = Prototype, R = Report, U = User scenario

[2] PU = Public, PP = Restricted to other programme participants (including the Commission Services), RE = Restricted to a group specified by the consortium (including the Commission Services), CO = Confidential, only for members of the consortium (including the Commission Services)

Consortium

Participant n°	Participant organisation name	Participant short name	Organisation type	Country
1 (Coordinator)	Luxembourg Institute of Science and Technology	LIST	Research	Luxembourg
2	Luxembourg Institute of Health	LIH	Research	Luxembourg
3	Associação Fraunhofer Portugal Research	FhP	Research	Portugal
4	Sonae Center Serviços II, S.A.	SONAE	Company	Portugal
5	Santa Casa da Misericordia do Porto	SCMP	End-user	Portugal
6	Gociety Solutions	GOC	Company	Netherlands
7	Unie KBO	KBO	End-user	Netherlands
8	cereneo Schweiz AG	CER	Company	Switzerland
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INTRODUCTION

This ethical roadmap is a strategic plan containing the basic principles and agreements that all project partners need to comply with during the LIFANA project, which main goal is to develop and evaluate the LIFANA Nutrition Solution to support healthy nutrition through all phases of ageing – from active seniors to elderly users and patients in need of daily care. Thus, this document focuses on ethical aspects in research involving elderly people. This ethical road map is also the foundation for the field trials.

In this deliverable, D3.2, the national ethics guidelines and procedures of Portugal, the Netherlands, and Switzerland will be documented. It also outlines the schedule and required documents that are necessary for the responsible national ethics commissions to approve the field trials. Since the collection and processing of data plays an important role in the project., attention is given to the EU legislation on data protection, the General Data Protection Regulation (GDPR, Regulation (EU) 2016/679), recently entered into force in Member States through National Law.

LEGISLATION AND GENERAL ETHICAL PRINCIPLES OF LIFANA

General Ethical Principles LIFANA

LIFANA will uphold the following six general ethical principles:

1. Respect for the integrity and dignity of persons (protecting them from being used for any other purpose than stipulated).
2. Follow the "do no harm" principle. Any potential risks must be clearly communicated to the person involved (be this the older person as research participant, caregivers or other stakeholders in the project).
3. Acknowledge the rights of individuals to privacy, personal data protection and the freedom of movement.
4. Honour the requirement of informed consent and continuous dialogue with the participant.
5. Respect the principle of proportionality: not imposing more than is necessary on the subjects, nor going beyond stated objectives (mission creep).
6. Treat societal concerns seriously – listen to the public/older person and engage with them in a constructive dialogue, transparently, honestly and with integrity.

Moreover, the members of the Consortium declare that the project will comply with the current legislation and regulations of the countries in which the research will be conducted, and with all relevant EU legislation. The following sub-sections summarize the most relevant legislation to which the research conducted within the LIFANA project will adhere.

The European Charter of Fundamental Rights

'The Charter of Fundamental Rights of the EU' brings together in a single document the fundamental rights protected in the EU. The Charter contains rights and freedoms under six titles: dignity, freedoms, equality, solidarity, citizens' rights and justice' (EU, 2013). The Charter became legally binding in 2009 when it was signed together with the Treaty of Lisbon. Meaning that all European legislation needs to conform to the principles of the Charter, including research policy. Several principles of the Charter are relevant in the context of research policy and are depicted below, as extracted directly from the Charter:

Article 3 – Right to the integrity of the person (dignity)

1. 'Everyone has the right to respect for his or her physical and mental integrity.
2. In the fields of medicine and biology, the following must be respected in particular:

(a) the free and informed consent of the person concerned, according to the procedures laid down by law;
(b) the prohibition of eugenic practices, in particular those aiming at the selection of persons;
(c) the prohibition on making the human body and its parts as such a source of financial gain;
(d) the prohibition of the reproductive cloning of human beings.'

Article 7 – Respect for private and family life (freedoms)

‘Everyone has the right to respect for his or her private and family life, home and communications’.

Article 8 – Protection of personal data (freedoms)

‘Everyone has the right to the protection of personal data concerning him or her’.

Such data must be processed fairly for specified purposes and on the basis of the consent of the person concerned or some other legitimate basis laid down by law. Everyone has the right of access to data which has been collected concerning him or her, and the right to have it rectified.

Compliance with these rules shall be subject to control by an independent authority.’

Article 25 – The rights of the elderly (equality)

‘The Union recognises and respects the rights of the elderly to lead a life of dignity and independence and to participate in social and cultural life.’

Article 38 – Consumer protection (solidarity)

‘Union policies shall ensure a high level of consumer protection’.

Declaration of Helsinki

The Declaration of Helsinki was developed by the World Medical Association (WMA) to lay out ethical principles for medical research involving human subjects. It is seen as the cornerstone of human research ethics in the world. Even though this is not a legally binding document through international law, most legislation of different levels have based their ethical principles on this Declaration and should therefore be highly respected. Relevant articles include (WMA, 2008):

Article 6: ‘In medical research involving human subjects, the well-being of the individual research subject must take precedence over all other interests’.

Article 11: ‘It is the duty of physicians who participate in medical research to protect the life, health, dignity, integrity, right to self-determination, privacy, and confidentiality of personal information of research subjects’.

Article 14: ‘The design and performance of each research study involving human subjects must be clearly described in a research protocol’.

Article 15: ‘The research protocol must be submitted for consideration, comment, guidance and approval to a research ethics committee before the study begins’.

Article 21: ‘Medical research involving human subjects may only be conducted if the importance of the objective outweighs the inherent risks and burdens to the research subjects’.

Article 23: ‘Every precaution must be taken to protect the privacy of research subjects and the confidentiality of their personal information and to minimize the impact of the study on their physical, mental and social integrity’.

Convention on Human Rights and Biomedicine of the Council of Europe

This Convention was set up by the Council of Europe and signed in 1997, an additional protocol was signed in 1998 on the prohibition of cloning human beings. This convention is also amended in the EU Lisbon Treaty in 2009. Relevant articles include (Council of Europe, 1997):

> **Article 1**: 'Parties to this Convention shall protect the dignity and identity of all human beings and guarantee everyone, without discrimination, respect for their integrity and other rights and fundamental rights with regard to the application of biology and medicine'.
>
> **Article 2**: 'The interest and welfare of the human being shall prevail over the sole interest of society or science'.
>
> **Article 5**: 'An intervention in the health field may only be carried out after the person concerned has given free and informed consent to it'.

EU General Data Protection Regulation (GDPR)

According to the Charter of Fundamental Rights of the European Union, natural persons have the fundamental right to the protection of personal data concerning him or her. In terms of controlling personal data and in order to build and maintain trust in online environment, the adopted new regulation states that easier access to personal data is ensured. Furthermore, EU citizens have the right to data portability, which means that data can be transferred between services by the user. Thereby, trust is strengthened, and fair competition created: especially small-and medium-sized businesses can compete with giants within the single market. The right to be forgotten means that if requested, data about a user must be deleted on her/his command. Moreover, users have the right to know when data has been exposed to unauthorised parties. In case of data breaches, the data protection authority of each Member State, as well as the user, need to be informed as soon as possible – where feasible within 72 hours.

All in all, the adapted Regulation ensures:

- Enhancing transparency
- Fostering consumers' trust
- Boosting competition through new right of data portability
- Creation of a level playing field for all companies active in the single market

The Council adopted the General Data Protection Regulation (GDPR) and Data Protection Directive on 8 April 2016. The Regulation and the Directive were adopted by the European Parliament on 14 April 2016. The Regulation (EU) 2016/679 (General Data Protection Regulation), repealing Directive 95/46/EC, entered into force on 24 May 2016 and applies since 25 May 2018. Directive (EU) 2016/680 (Data Protection Directive) entered into force on May 5, 2016 and applies since 6 May 2018.

Regulation (EU) 2016/679 *of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation) (Text with EEA relevance).*

Article 5: **Principles relating to processing of personal data.** These include: lawfulness, fairness and transparency; purpose limitation; data minimisation; accuracy; storage limitation; integrity and confidentiality; accountability.

Article 7: **Conditions for consent.** Where processing is based on consent, the controller shall be able to demonstrate that the data subject has consented to processing of his or her personal data. The data subject shall have the right to withdraw his or her consent at any time.

Article 9: **Processing of special categories of personal data**. The processing of data concerning health shall be prohibited, except the data subject has given explicit consent to the processing of those personal data for one or more specified purposes.

Article 15: **Right of access by the data subject.** The data subject shall have the right to obtain from the controller confirmation as to whether or not personal data concerning him or her are being processed, and, where that is the case, access to the personal data.

Article 16: **Right to rectification**. The data subject shall have the right to obtain from the controller without undue delay the rectification of inaccurate personal data concerning him or her.

Article 17: **Right to erasure ('right to be forgotten').** The data subject shall have the right to obtain from the controller the erasure of personal data concerning him or her without undue delay.

Article 20: **Right to data portability.** The data subject shall have the right to receive the personal data concerning him or her, 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 without hindrance from the controller to which the personal data have been provided.

Directive (EU) 2016/680 *of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data by competent authorities for the purposes of the prevention, investigation, detection or prosecution of criminal offences or the execution of criminal penalties, and on the free movement of such data.*

Directive 2009/136/EC *of the European Parliament and of the Council of 25 November 2009 amending Directive 2002/22/EC on universal service and users' rights relating to electronic communications networks and services, Directive 2002/58/EC concerning the processing of personal data and the protection of privacy in the electronic communications sector and Regulation (EC) No 2006/2004 on cooperation between national authorities responsible for the enforcement of consumer protection laws (Text with EEA relevance)*

Directive 2002/58/EC: *Concerning the processing of personal data and the protection of privacy in the electronic communications sector (Directive on privacy and electronic communications, e-privacy). Especially focused on the protection of individuals with regard to the processing of personal data and on the free movement of such data.*

On 16 November 2018, the European Data Protection Board has published **Guidelines 3/2018 on the territorial scope of the GDPR (Article 3)**1.

Political background and motivation

The Eurobarometer survey on protection and personal data, conducted among 28.000 EU citizens in March 2015, reveals concern among EU citizens. For example, a majority agrees that 'providing personal information is an increasing part of modern life' (71%), 'that their explicit approval should be required in all cases before their data is collected and processed' (69%), or 'that they would want to be informed should their data ever be lost or stolen'. Further, eight out of ten EU citizens feel that they do not have complete control of their personal data.

GDPR applies adapted regulations, which build and maintain trust. The overall change concerns the same data protection rights across EU. This means for businesses that the single, pan-European law for data protection build consistency between 28 countries. Moreover, one-stop shop involves one single supervisory authority (Data Protection Authority, DPA), which will promote clarity and make it cheaper for companies to do business in the EU. Same rules apply when goods and services are offered on the EU market. By means of a risk-based approach, rules will be tailored to risks and therefore avoid one-size-fits-all obligation. Rules incentivise businesses to innovate, by means of data protection by design, meaning to build data protection safeguards into products and services from the earliest stage of development. Techniques as anonymisation, pseudonymisation and encryption are promoted to protect personal data (important in terms of big data) and thereby enable big data innovation. Transparency is core to the adapted version on data protection, stating that organizations should publish transparent and easily accessible data protection policies. 'Simple icons on a website could explain how, by whom and under whose responsibility personal data will be processed' (European Commission, 2016).

All in all, red tape will be reduced, meaning that no more notifications (fees for processing data) need to be provided to supervisory authorities. Small-and medium-sized businesses are for example also able to charge a fee for providing access to data. Data protection officers do not need to be appointed by the large majority of small-and medium-sized businesses. Only when the core activities involve 'regular and systematic monitoring of data subjects on a large scale' does a data protection officer need to be appointed. Only very risky data processing activities need to carry out data protection impact assessments. Thereby, a privacy-friendly environment will be created.

In addition, nothing in the LIFANA project may conflict with the opinions of the European Group of Advisors on 'the Ethical Implications of Biotechnology and concerning respect of human person' (1991-1997) and the opinions of the European group on 'Ethics in Science and New technologies' (as of 1998).

Relevant National Regulations

As mentioned above, within LIFANA, user research and pilot trials will be carried out by some or all project partners. Therefore, LIFANA does not only take account of the EU regulations, which

[1] https://edpb.europa.eu/our-work-tools/public-consultations/2018/guidelines-32018-territorial-scope-gdpr-article-3_en

are relevant to healthcare research with human subjects, but will also consider the following national legislation.

The Netherlands

- Wet Bescherming Persoonsgegevens (WBP) / Personal Data Protection Act (6 July, 2000)
- Wet medisch-wetenschappelijk onderzoek met mensen (WMO) / Law on medical research with human subjects (26 February, 1998)

Portugal

- Lei da Protecção de Dados Pessoais (Lei n.º 67/98, October 1998)
- Currently, the new proposed law ('Proposta de Lei n.º 120/XIII') is under discussion with stakeholders in the country.
- Note: Fraunhofer Portugal has hired the services of a specialised company that is assisting the organisation in following the highest standards with regards to data protection. This applies not only to the organisation, as well as to the work being developed within the projects, as is the case of LIFANA.

Switzerland

- Bundesgesetz über den Datenschutz (DSG) vom 19. Juni 1992 (Federal Act of 19 June 1992 on Data Protection)[3]
- Data Protection Ordinance (DPO)
- Note: on 13 July 2018 the jurists of the Swiss Ethics Committees have laid down the further procedure regarding the applicability of the general data protection regulation (GDPR) to the human research in Switzerland. In principle, it can be assumed that the principle of equivalence between the Swiss law and the EU regulation applies and that patients in Switzerland do not need to be additionally and newly informed about the European data protection rights. It is up to the sponsor and the hospital to determine in each individual case whether or not the GDPR is applicable or not to a clinical trial or a research project. If the sponsor and the hospital should envisage to inform the study participants about the GDPR, then the information must be submitted in the form of an addendum to the informed consent. This addendum is only acknowledged by the study participants and is therefore not a consent from a legal point of view. Consequently, this addendum must be submitted to the ethics commissions for information only, but not for approval. However, the ethics commissions may request corrections to the documents before acknowledging them. Long and incomprehensible explanations or, for example, naming the Federal Data Protection Commissioner for questions or complaints are not accepted.

As national regulations might adapt within the following years, due to GDPR, the LIFANA Consortium declares to stay up-to-date with adaptations of relevant national regulations in each country.

[3] https://www.admin.ch/opc/de/classified-compilation/19920153/index.html

RECRUITMENT OF THE PARTICIPANTS & INFORMED CONSENT

Each organisation (KBO PCOB, FhP, SCMP, CER/CEFIR) will use their own contacts and recruitment methods. The recruitment method will have to comply with the methods and targets of the investigation.

Potential participants will be informed about what they can expect during the research. This information will be handed out to the participants in written form by means of an information sheet. Potential participants w

Reinforced by Regulation (EU) 2016/679, informed consent will be notified in their own language, and in a comprehensible way, about the research targets and methods. The researchers will make future participants aware that their participation is completely voluntary, that they have the right to refuse to participate, and that they can terminate their participation without the need to justify their decision. The researchers will inform participants on a number of important factors that may influence their decision to participate (such as risks, inconveniences, potential adverse consequences or restrictions to confidentiality) and they will elaborate on any other aspect on which the future participant may have a question. The researchers will inform participants on the feedback report method and the nature of the research results that will be reported or published. The participant shall get ample opportunity to read through the information, to ask the researcher any questions and to consider their potential participation. As the LIFANA project will treat health data - which must be treated as sensitive data, this will be communicated explicitly. For example, it includes the statement that personal data will not be processed for other purposes by third parties (e.g. health insurances or banking companies).

The LIFANA project will not approach people who are unable to give their informed consent. Participants, who, after being approached are assessed as incapable of making rational and voluntary decisions, will be excluded from the LIFANA research activities

In order to recruit participants, no unsuitable high financial compensations nor any other rewards may be used. It is nonetheless allowed to give participants a small and suitable token of appreciation. The costs for expenditure related to participation will be paid by the organization conducting the recruitment.

Should the research require the involvement of participants who have specific problems, for instance with specific diet requirements or health issues, the researchers will first have to address these issues before recruiting these individuals for the research. This will be done by using an appropriate and short standardized questionnaire in the field trials phase. In case of any doubt the researchers need to consult experts on the issue (such as a medical doctor or a dietitian) specialized in the field concerned.

In summary, the informed consent document will cover the following aspects:

1. Purpose of the project
2. Research procedures and purpose
3. Duration
4. Benefits for participants, society and economy
5. Potential risks

6. Alternatives to participation
7. Incentives for participation
8. How data will be processed and by whom
9. Participation rights: Refuse or withdraw of participation
10. Data protection and privacy
11. Research results and publishing
12. Recording, pictures and videos
13. Emergency care, compensation for injury or damage

DATA PROTECTION AND PRIVACY

According to Regulation (EU) 2016/679, with which LIFANA is compliant, the same data protection rights across the European Union apply in the European-wide project LIFANA. Data protection and privacy are fundamental rights, which need to be respected. Privacy covers the right to manage one's personal information, while being free from secret surveillance. Data protection entails the integrity and control of one's data with regard to the purposes of data processing.

As the LIFANA project involves partners from different countries in the European Union, personal data need to be processed across borders inside the European Union. Due to the adopted Regulation (EU) 2016/679, protection safeguards will be implemented from the earliest design stage of the project and will be observed during the course of the LIFANA project. Therefore, each entity will store their own data in order to prevent cross-border processing. Furthermore, personal data will be anonymised/pseudonymised/encrypted in order to protectively process the data. Core to the data protection and privacy regulations in the LIFANA project is transparency, meaning that data protection policies will be published. On top of that, in order to comply with the adapted Regulation (EU) 2016/679 and to build trust between the services provided by the LIFANA project and its end-users, data accessibility will be applied. This means that users will get access to their personal data, if requested. Further, users can ask for their personal data for data portability use, enabling them to easily transfer their data to other services. If requested, personal data will be deleted once and for all.

Particularly in terms of data protection, the data protection authority of each Member State as well as the user will be as soon as possible – where feasible within 72 hours – informed in case one's personal data have been exposed to non-authorised third parties.

A main rule for businesses, either employing 250 employees or whose core activities involve processing data on a large scale, is that they are obliged to designate a data protection officer, either as a full-time employee or as an ad-hoc consultant. This designated data protection officer is responsible for all tasks, relating to data protection and acts as the contact point for the supervisory authority. However, in the LIFANA no data protection officer needs to be announced, as neither data of special categories nor data on a large scale will be processed (Regulation (EU) 2016/679, Article 37, no. 1 b), c)). Because of the nature of the data, data protection impact assessments will not be conducted. However, the LIFANA Consortium will stay informed about any changes and will adapt accordingly. In addition, only data will be processed after informing research participants and obtaining a signed informed consent. As a final remark, the partners in the LIFANA project are obliged to respect data protection laws in place within their country, which naturally enforces compliance within the LIFANA project.

Since three countries, Portugal, the Netherlands and Switzerland are involved in the user research activities requiring data collection from humans, each partner will ensure compliance with its data processing activities and will be monitored by the supervisory authority of its country (Regulation (EU) 2016/679, Article 51).

Processing and storage of personal data

Personal data is defined as any piece of data regarding an identified or identifiable natural person, for example date of birth, gender, address.

- The LIFANA Consortium will handle personal data confidentially and will abide by all applicable legislation.
- The privacy of all participants will be respected by giving control over the processing of personal data. Personal data that may lead to the identification of a participant will be disconnected from the research data.
- Personal data gathered for LIFANA will only be used for its assigned goals defined in advance, or for objectives that are consistent with these defined goals.
- Members of the LIFANA Consortium will not hand over any personal data to any third party, without the participant´s prior written and clearly stated consent. Even so, passing personal data to any third party is only allowed if this would serve the LIFANA research.
- If a database with directly identifiable personal data will be constructed within LIFANA, the researcher must provide its registration according to national rules.
- The researchers will take all suitable precautionary technical and organisational measures to prevent any loss of data or illegitimate access or processing.

Given that the purpose of LIFANA system is to offer personalize meal recommendations, storing personal data is necessary. Two distinct categories of data will be stored on partners' servers: mandatory data, and optional data. Mandatory data is required for the proper functioning of the system, and includes anthropometric data, such as height, weight, age, and activity level. The email address and password will also be stored since they are required for authentication before the system. The password will be stored in an encrypted format so that it is not even revealed to the LIFANA system administrators. Optional data includes dietary restrictions, name, food preferences, eating habits, allergies, and shopping lists. The system will work without this data; however, the quality of the recommendations will be limited without this information. On the first login users will be required to fill in the basic and mandatory information. Users will be able to correct or complement the information at any time. The GoLive Phone suite of applications may also have access to different personal information about its users, including their contacts, care givers, and self-reported medication. Users' physical activity level may also be monitored either using the smartphone or the GoLive clip wearable device. SONAE will also handle user personal information including their identification and address to be able to deliver groceries to LIFANA users. This is performed through an explicit request of the users in case they want to take advantage of the online shopping service, in this case, the shopping list that has been compiled by the user will be made available to the external shopping application operated by the Portuguese retailer Continente that is operated by SONAE.

User Data will be physically stored both on their personal smartphone as well as in the cloud. The communication between the smartphone and cloud will be carried out over end-to-end encryption (HTTPS). The servers will be located in FhP's own premises and on servers managed by Gociety, and on servers managed by SONAE, all located within the European Union. Only researchers involved in the LIFANA project will have access to the data. FhP's IT department can have access to the servers for maintenance purposes.

Handling of missing data

Data of participants that drop out before the trial start – e.g. because of withdrawal of consent – will not be included into the study. However, data on the reason for dropping out will be collected and stored. If the participant is excluded during the course of the field trial, the data of the trial completed so far may be used for the final analysis. If the participant withdraws his/her consent during the course of the field trial, the anonymized data of the trial completed so far may also be used for the final analysis.

If a participant fails to take part in one (or more) of the planned sessions (for whatever reason), the respective dataset will be marked as missing, and the study protocol will be continued without alterations. As mentioned above, her or his data may still be used for the final analysis.

APPLYING ETHICAL PRINCIPLES TO THE LIFANA PROJECT

In this chapter a description is provided about how the ethical principles mentioned before are applied across the different research parts within LIFANA.

User Integration

For every activity which involves users – from co-creation workshops to everyday field trials, an informed consent will be provided to participants.

Co-creation

At this phase of the project, the consortium partners will already have existing technology which will be individually improved and integrated with one another in order to for the comprehensive offer of the LIFANA Nutrition Solution. This technology can be used as stimulus for the participants. Furthermore, other techniques will be used to elicit requirements from the participants, drawing on their everyday lives' experiences, their needs and aspirations. The consortium has agreed to conduct workshops and/or focus groups in Portugal, in the Netherlands and in Switzerland.

The data being collected in the workshops does not require linkage to participants' names, given that the user research is mostly looking for the participants' perspectives and insights as a group. The approach will be of qualitative nature and the data collected will consist of observation notes, tangibles produced by the participants and visual recordings of the sessions.

Participants will be offered the opportunity to receive the outcomes emerging from the analysis of workshop data and, whenever possible, will be asked whether they would be interested in participating in later stages of user integration: usability evaluation and everyday field trials.

Usability evaluation

Usability evaluation will accompany the technical development activities; therefore, researchers will conduct formative usability tests with participants while the system is being developed and summative tests when a full-fledged version is implemented. The usability tests may start with paper prototypes, move to semi-functional mock-ups simulating final interactions and end with the final prototypes.

The consortium will use different methods for this evaluation, such as interviews, workshops, focus groups and formal usability tests either in a controlled environment or in the field. We anticipate that, from this phase onwards, participants will me more involved in the project due to the expected frequency of usability verifications. We aim to adopt participatory design frameworks to the widest possible extent.

Everyday field trials

The third and last phase of user involvement consists of technology assessment in the field, introducing LIFANA Nutrition Solution in participants' everyday lives and evaluate the system in

these conditions. This will provide insights on needs for feature adjustment, validation of efficiency, efficacy and satisfaction, as well as impact of the system on people's lives.

The design of the field trials study (methodology, number of participants) is described in detail in Deliverable D3.3 "Field Trials Study Design". The research methodology may vary between countries, as the type of users will differ. In Portugal and the Netherlands, the type of users involved will be elderly that are considered independent, while in Switzerland, the involved users will be users with need of dedicated nutritional care after discharge from a clinic. During this stage, participants will be receiving nutritional recommendations from the LIFANA Nutrition Solution, which is the most challenging aspect regarding ethics. For this reason, the field trials are planned in such a way that the recommendations are monitored by professionals, so that there is no hazard risk for participants.

In long term field trials with technology, technical problems are likely to happen. Therefore, the teams in the field will be trained to enable support to research participants and the technical partners will set up a help desk to provide technical support on demand.

The field trials will be overseen by partner LIH – an organisation with an extensive experience in conducting field trials. The plans for these field trials include the establishment of a person's baseline and a follow-up. The procedures for the field trials will be submitted to local ethics committees for discussion, comments and approval of the LIFANA consortium's plans.

Participants will be thoroughly informed, both written and verbally in a special information session for the recruited participants. After this session they will have enough time to consider the project and make their decision for participation. When participants agree to participate, they will have to sign the informed consent form to ensure they have understood the anticipated risks and benefits that are attached to this research. Furthermore, the legal liabilities are clearly outlined, in particular for privacy and data protection.

Possible Risks

The partners do not foresee major risks for participants associated with their involvement in the LIFANA project, as non-invasive, non-pharmacological interventions are used. Nevertheless, even if not constituting major hazards, there are risks which we can anticipate and for which we have devised avoidance or mitigation strategies. We shall focus on the activities of usability evaluation and in everyday field trials, as these are the ones posing risks. These risks, as we anticipate them, will be part of the explanation provided in the informed consent forms provided to participants.

It is natural to give priority to risks associated with older adults using the system due to an association with vulnerability. However, in the scope of the LIFANA project, not only older adults, but also professional caregivers are involved as direct users of the system. The professional caregivers – dietitians/nutritionists are also exposed to risks.

Already in place are the following measures: the definition of Ethical Procedures (this deliverable) as a set of golden rules for researchers involved in the project; definition of all the scenarios of use to anticipate possible problems and challenges in interaction; unit and integration tests to guarantee that the technology is safe and shows good performance; ethics leadership by the leader of WP3.

During the **usability evaluation phase**, the risks we anticipate are not related to body parts, but to mental state. Should recruited participants be novice technology users, the technology and multiple requests to take part in the activities may impose mental burden and frustration. In order to avoid these minor risks, all researchers going out into the field to moderate these usability evaluation sessions must be trained professionals to deal with these settings and with vulnerable populations. Furthermore, when relevant, users may receive training on the use of mobile devices to reduce the likelihood of burden and frustration.

During **everyday field trials** there are greater risks due to unsupervised use of technology for long periods and to risk of unsuitability of nutritional recommendations provided by the system. The first measure in place to prevent these risks is the screening for recruitment – only people who are proven capable of making decisions will be considered eligible to participate. The initial screening of participants shall also include a professional analysis of candidates' nutritional status and record of medical conditions which might render their participation impossible. Should the participants be considered eligible, their food restrictions, preferences and personal characteristics will be recorded so that the system can adjust its recommendations to this profile. These are all measures to minimise risks regarding the recommendations provided by the system. The inclusion and exclusion criteria will be detailed in ***Deliverable 3.4 – Field trials study design***.

The technology being used consists of an off-the-shelf smartphone (or tablet), which is certified with CE marking and, therefore, safe to use. The consortium considers including research participants who already own these devices, which can be used to install the LIFANA Nutritional Solution software. Therefore, in terms of hardware being used, we anticipate no serious risks for participants. The software in itself – the interaction with it – may cause the burden and frustration we anticipated for the usability evaluation. In this case, the same procedures will be adopted.

The technological solution being provided to the users is also a service regarding nutrition. In this case, one possible risk is that users become dependent on using the system, especially since they will be using it for an extended period of time. The system is expected to bring measurable and self-perceived benefits regarding physical and material well-being. A sudden or uncontrolled end of the trials might lead to inconvenience for the participants or, when gains were observed, to a return to previous unhealthy eating habits. Therefore, the field trials are so prepared that the users will be able to continue using the software on their smartphones after the trial period end. The cloud-based service facilitates the availability of the solution. The partners conducting the recruitment will make it clear to participants what the conditions for participation are and will seek to provide second line support for validation of recommendations provided by the system.

All adverse events will be collected, fully investigated and documented. Documentation will include dates of event, resolution, assessment of seriousness and causal relationship to the intervention and/or study procedure.

Possible Benefits

Even prior to testing the nutritional recommendation system, participants can already benefit from being involved with the LIFANA project. During the co-creation and usability sessions, participants will necessarily learn about nutrition, discuss doubts they might have and have time to reflect and discuss amongst themselves about their eating habits and food choices. This, we contend, increases awareness of health status and increases health literacy which is instrumental to a good quality of life.

Nutritional awareness and health literacy are coupled with an increased knowledge about digital technology – participants will interact with mobile devices and with software applications. The use of a participatory design approach enables users to be part of the process, feel close to the research and development team, and socialise with both researchers and other participants. The trust relationships that are necessarily created enable participants to clarify doubts with researchers and vocalise their concerns, which can be tapped onto early on. The sense of belonging to the team and of being a contributor to the technology are benefits brought about by participatory design.

Within a thoroughly tested system and validation of nutritional recommendations by dietitians, we anticipate that increased quality nutrition is one of the major benefits for participants during the everyday field trials. Participants will furthermore be empowered to make better informed decisions about their food ingestion and will have the benefit of access to high quality nutrition within a limited budget, which brings the benefit of financial savings.

Reports

The dissemination and publication of the results obtained are two of the primary aims of scientific researchers. Publishing research results also involves a conflict between the privacy interests of individual participants 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. For example, on issues previously discussed such as privacy, data protection and anonymity. The Helsinki Declaration in its latest version (World Medical Association – Declaration of Helsinki) states the following (WMA, 2008):

> *'Authors, editors and publishers all have ethical obligations with regard to the publication of the results of research. Authors have a duty to make publicly available the results of their research on human subjects and are accountable for the completeness and accuracy of their reports. They should adhere to accepted guidelines for ethical reporting. Negative and inconclusive as well as positive results should be published or otherwise made publicly available. Sources of funding, institutional affiliations and conflicts of interest should be declared in the publication. Reports of research not in accordance with the principles of this Declaration should not be accepted for publication.*'

All partners in LIFANA will adhere to the Declaration of Helsinki. For statistical analysis, only anonymized data will be reported.

Evaluation

Research ethics requires an independent evaluation of the research activities and its possible consequences. It is a matter of awareness and looking beyond the research objectives, to consequences for everyone involved and the possible impact. This aspect will be considered in the final evaluation of the LIFANA project. In each participating country there are organisations which can provide advice and resources to support researchers in the LIFANA project. These organisations are listed by country below.

Netherlands

Centrale Commissie Mensgebonden Onderzoek (central committee for people research)
Parnassusplein 5
2511 VX Den Haag

Postal address:
Postbus 16302
2500 BH Den Haag

Tel.: +31 (0)70 340 6700

Website: www.ccmo.nlwww.ccmo.nl

Autoriteit Persoonsgegevens (Board for Personal Data Protection)
Bezuidenhoutseweg 30
2594 AV Den Haag

Postal address:
Postbus 93374
2509 AJ Den Haag

Tel.: +31 (0)70-8888 500

Website: http://www.autoriteitpersoonsgegevens.nl/

Portugal

Comissão National de Protecção de Dados (National Commission for Data Protection)
Rua de São Bento n.° 148, 3°
200-821 Lisboa

Tel.: +351 21 39 28 400

Website: https://www.cnpd.pt/https://www.cnpd.pt/

Switzerland

Ethikkommission Nordwest- und Zentralschweiz (EKNZ)
Hebelstrasse 53
4056 Basel

Tel.: 061 268 13 50
Fax: 061 268 13 51
Email: eknz@bs.ch

Website: https://www.eknz.ch/https://www.eknz.ch/

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