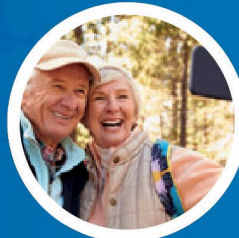


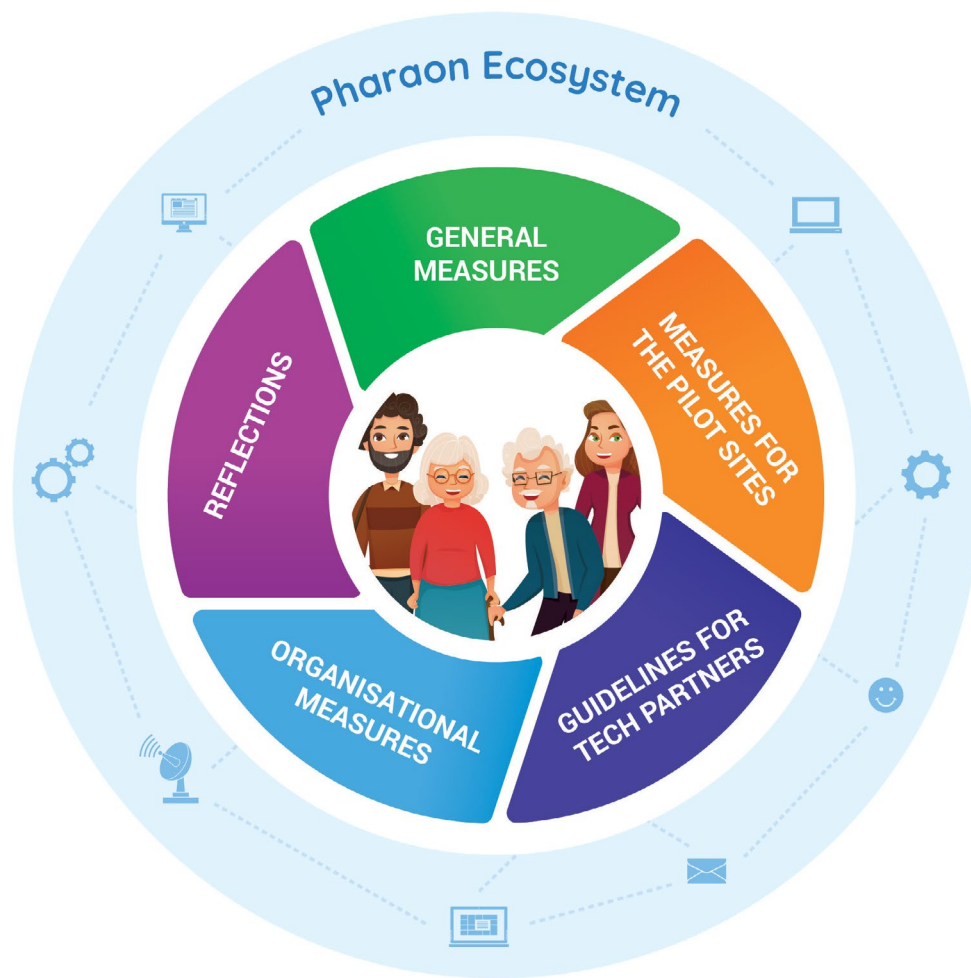
pharaon



Pilots for Healthy & Active Ageing



ETHICS MINIGUIDE



ARE YOU AWARE OF :

human participants rights protection in your country? *If not, please check the following page.*

☐

personal data privacy and security legislation? *If not, please check the following page.*

☐

the requirements needed to your national ethics committee approval?
If not, please check the following page.

☐

the ethical guidelines of Pharaon? *If not, please check the following page.*

☐

risks and threats to the participants rights and freedoms? *If not, please check the following page.*

☐

equality and justice tips for preparing the pilot? *If not, please check the following page.*

☐

measures regarding ethics in human research? *If not, please check the following page.*

☐

measures regarding data protection? *If not, please check the following page.*

☐

the co-creation methodology? *If not, please check the following page.*

☐

the guidelines to phone interviews? *If not, please check the following page.*

☐

REFLECTIONS

Which main societal challenges are clear in current times for Pharaon?

Apart from national policies and deontology, check out some reflections on:

THE MID-TERM EFFECTS OF COVID-19

DATA SHARING GOVERNANCE FOR OLDER ADULTS

WORKFORCE CHALLENGES WITH THE DIGITAL REVOLUTION

GENERAL MEASURES

Pharaon has a very complex, yet fascinating ecosystem!

To guarantee all older adults are protected, namely the more vulnerable ones, and not stigmatized but valued, see the measures you should follow regarding:

AGEISM

ACCESSIBILITY

CO-CREATION

EXIT STRATEGY

TRAINING

INCIDENTAL FINDINGS

GDPR

MEASURES FOR THE PILOT SITES

Pilot sites are the closest partners to the older adults and caregivers and need to take several guidelines into consideration for their activities:

GENDER

SAFETY

VULNERABILITY

CONSENT

DIGITAL LITERACY

DIGITAL ACCESS

GUIDELINES FOR TECH PARTNERS

You think you have nothing to learn here? But you are mistaken!!

Go to the Pharaon's Ethical Guidelines and see what you may be missing to protect our final end-users in Pharaon.

ORGANISATIONAL MEASURES

Pharaon, as a whole ecosystem, will implement several measures to ensure, not only compliance, but Ethical excellence!

Go to the Pharaon's Ethical Guidelines and see what you may be missing to protect our final end-users in Pharaon.

TOOLS



Miniguide



Informed Consent package



Guidelines



Procedures to Obtain Informed Consent



Users tips



Ethics Dialogue Assessment



Matrix for use cases



Cáritas Coimbra - May, 2020



Pilots for Healthy & Active Ageing



ETHICAL GUIDELINES

TABLE OF CONTENTS

INTRODUCTION	7
THE PROCESS	7
THE ACTORS AND THE ACTIONS	7
THE GUIDELINES	8
THE TOOLS	9
REFLECTIONS	10
GENERAL MEASURES	11
AGEISM	11
ACCESSIBILITY	11
CO-CREATION	12
EXIT STRATEGY	12
TRAINING	12
INCIDENTAL FINDINGS	12
GDPR	12
MEASURES FOR THE PILOT SITES	13
GENDER	13
SAFETY	15
VULNERABILITY	15
CONSENT	15
DIGITAL LITERACY	15
DIGITAL ACCESS	15
TECHNICAL MEASURES	16
ORGANIZATIONAL MEASURES	18
TOOLS	20
USER TIPS	21
MATRIX FOR USE CASES	22
INFORMED CONSENT PACKAGE	27
PROCEDURES TO OBTAIN INFORMED CONSENT	34
ETHICS DIALOGUE ASSESSMENT	36



INTRODUCTION

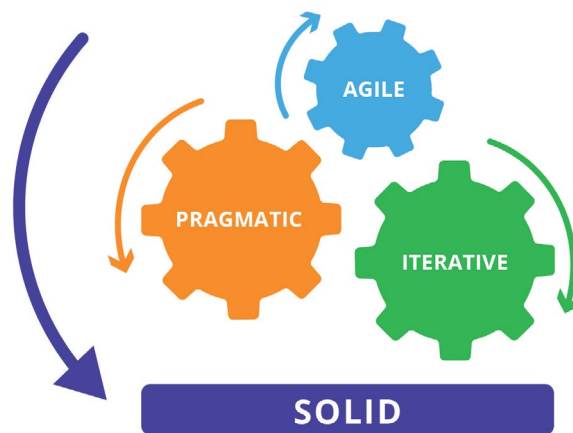
THE PROCESS



The consortium is aware that not only technological matters, e. g. artificial intelligence, hardware, software, systems integration should be considered, but also person-centered considerations and all the issues regarding individual and collective security and wellbeing are of high importance: ethical, privacy, legal considerations and deontological aspects are main aspects to address.

This implies that the Ethical approach within Pharaon must be:

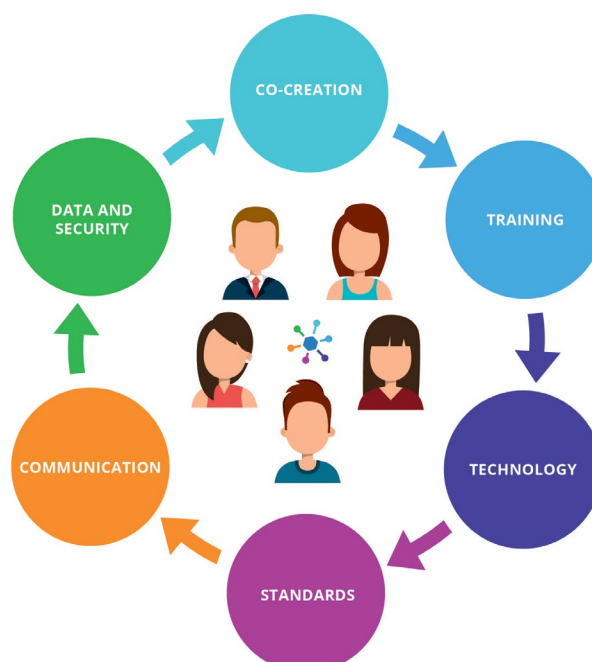
1. Iterative
2. Agile
3. Pragmatic
4. Solid



THE ACTORS AND THE ACTIONS



This iterative dialogue is implemented through a continuous conversation between the different stakeholders and a convergence between different work packages and activities:





REFLECTIONS

- Health and Care systems (differences in EU)
- National specificities on law and regulations
- Covid-19 effects
- Professional Ethics and Deontology
- Data Sharing Governance
- Workforce challenges with the digital revolution

GENERAL MEASURES

- Ageism
- Accessibility
- Co-creation
- Exit strategy
- Training
- Incidental findings
- GDPR

MEASURES FOR THE PILOT SITES

- Gender
- Safety
- Vulnerability
- Consent
- Digital literacy
- Digital access

GUIDELINES TO TECH PARTNERS

- Ethics as a framework
- Legal behaviour is not enough
- Human lives behind tech
- Additional risks for technological implementation
- Avoid islands of knowledge
- Keep the general picture in mind – Pharaon is an ecosystem
- Ethical Reflection
- Chain of ethical accountability
- Crisis simulations
- Consider users expectations
- Privacy and Security by design
- External experts
- Best practices and good models
- Data protection measures:
 - Access control
 - Integrity
 - Pseudonymisation
 - Encryption
 - Transmission control
 - Confidentiality
 - Recoverability

ORGANISATIONAL MEASURES

- Pharaon's main statements:
 - Values declaration
 - Vision declaration
- Pharaon's Ethics guidelines
- Ethics communication strategy
- Ethics training
- Ethics Board
- Ethics Manager
- Ethics helpdesk
- Ethics monitoring and periodic assessment
- Ethical leadership



The tools provided within Pharaon are directed to different publics and also to different levels of usage and interest:

1. ETHICS MINIGUIDE

Aggregates the areas and works as an interactive index to search and find the guidelines referring to each of the issues addressed.

2. PHARAON'S ETHICAL GUIDELINES

Provides a clear and focused, yet solid description of each of the specific measures recommended per ethics area.

3. USERS TIPS

Provides useful tips within the Ethics dimensions for older adults.

4. MATRIX FOR USE CASES

Exemplifies potential questions to be discussed between pilot sites, users and providers in order to elicit all the issues to be raised, to understand if they are all addressed in the use cases and to assess which are (or not) blocking issues and to which degree.

5. INFORMED CONSENT PACKAGE

Includes the factsheet, IC template and revocation form.

6. PROCEDURES TO OBTAIN INFORMED CONSENT

Gathers the procedures to be applied in the pilot sites to obtain informed consent, including the guidelines to collect consent in emergency situations.

7. ETHICS DIALOGUE ASSESSMENT

Provokes an iterative dialogue and periodic assessment of the best practices applied in the pilot sites (to be used by sites initiative or requested in specific check point dates).

REFLECTIONS

Health and Care systems (differences in EU)

There are societal challenges that pilot sites in Pharaon will be asked to assess and include in their reflections for implementation, that will be addressed through the ethical dialogue method proposed in section 5 of D10.5.

National specificities on law and regulations

In Pharaon's D10.2, Legal and ethical requirements for trial sites, a dedicated analysis of relevant legal framework of the different pilot sites is presented, although still in a preliminary phase. Some additional reflections for implementation will be further developed within the project, as detailed in the ethical dialogue addressed in section 5 and will be complementary to the work of WP8 – exploitation.

Covid-19 effects

This chapter mainly intended to advise pilot sites, but also all technical partners, that Pharaon can take advantage of the societal changes brought by the Covid-19 pandemic to embed the new needs and challenges into its plans.

Professional Ethics and Deontology

Both perspectives have positive aspects and shortcomings and it is important that Pharaon's is able to build an intermediate proposal that can illustrate to partners how they ought to behave within their professional practices, taking into account both deontological norms and an ethical dialogue.

Data Sharing Governance

One essential dimension is the discussion on the following questions: the citizen's right to access and share his/her own data; the citizen's will and knowledge to do so; and the system's tools that can allow such an effective interaction. Pharaon will have this as a relevant area to explore, either by proposing stakeholder high-level discussions, but also by bringing these to a low-level conversation with pilots participants and different project partners.

Workforce challenges with the digital revolution

Pharaon will make a reflectional analysis throughout the project, addressing the most relevant needs that ensure that the introduction of technology is well-accepted and reduces the burden of professionals – not increasing their anxiety or workload, namely:

- the analysis of the structural changes that may be needed in health care settings to support the workers in the digital revolution
- the investment in training and education, providing skills to the health and care professional in order to maximize the benefits of digital technologies
- the promotion of EU and Member State policies that support health and care workforce in the scaling-up of innovation

GENERAL MEASURES

AGEISM



Ageism influences how we feel (prejudice), think (stereotypes) and act (discrimination) about and towards older people and leads us to internalise stereotypes, prejudices, and discrimination until we end up embodying them and become that older person. The Pharaon project will work not to perpetuate this type of discrimination, by recommending to use the term “older adults” instead of the “elderly”, for example. This recommendation has been provided, from the beginning of the project, by AGE Platform as Dissemination Manager to all partners. It is also reinforced by the Ethics guidelines provided to pilot sites and to all the partners and will be considered in all the revisions by the Ethics Chair and in the materials provided and released within the project.

ACCESSIBILITY



In Pharaon, several accessibility perspectives can be ensured. Two specific measures are already foreseen – one on the area of standards and one other related to dissemination. In this initial point, specific recommendations for the creation and use of accessible documents and outputs will be released.

A document is considered accessible if it meets certain technical criteria and can be used by people with disabilities. This includes access by people who are mobility impaired, blind, low vision, deaf, hard of hearing, or who have cognitive impairments.

Making Pharaon documentation and outputs accessible makes it easier for people with disabilities to read them with and without the aid of assistive technology software and devices such as screen readers, screen magnifiers, text-to-speech software, speech recognition software, alternative input devices, Braille embossers, and refreshable Braille displays.

When creating accessible documents, there are steps that should be followed in order to assure the content is accessible. Broadly, these are the characteristics of accessible documents:

- Scannable
- Searchable
- Legible
- Readable
- and follow these 6 Core Skills:
 - Headings and document structure
 - Hyperlinks
 - Video captions
 - Bullets and numbered lists
 - Color and contrast
 - Image alt-text

Making documents with accessibility in mind means that Pharaon is trying to ensure that its content can be read and understood by the wider audience possible.

The links and tools below provide support towards accessibility implementation within Pharaon:

<https://www.adobe.com/accessibility/pdf/pdf-accessibility-overview.html>

<https://www.washington.edu/accessibility/documents/>

<https://abilitynet.org.uk/factsheets/creating-accessible-documents-0>

<https://accessibility.umn.edu/tutorials/documents>

<http://ncdae.org/resources/cheatsheets/>

CO-CREATION



Participation is empowerment and Pharaon will have a co-creation framework throughout the whole project, as explained in more detail in D10.2 and detailed in WP2 outputs.

Co-creation is a form of collaborative innovation: ideas are shared and improved together, with all ecosystem's actors, especially the end-users.

EXIT STRATEGY



An exit strategy is an ethical procedure to prevent end users from generating dependencies to the solutions or products they have been using during their involvement into the project, mainly when they are in vulnerable situations or frail conditions. Exit strategies should be built into the design of projects from the outset and should be considered to ensure that its results will remain available to its beneficiaries even after it has ended. A good risk assessment, proactive communication policy and establishing an independent complaints procedure are some suggested ways to head off problems. Pharaon will also provide alternative resources (like informal training) for pilot sites to reach out to in case any related issues emerge.

TRAINING



For partners

In Pharaon, training will be especially targeted to provide different partner workers with additional knowledge on the Ethics area. Concertation activities with networking and training activities of relevant projects – e.g. COST Actions such as SHELD-ON (grant holder is CETEM) or AGE4NETFRIENDLY (grant holder is CDC) will be a relevant asset to provide expertise and training, also for early career researchers and can effectively benefit Pharaon's collaborators with adequate knowledge.

For older adults

Although digital tools use will be supervised by caregivers, Pharaon intends to prepare their target group for future autonomous use of technologies. Thus, training on digital security is foreseen as part of the pilots preparations and will be developed in articulation with WP9, as leaders, and the technical partners.

INCIDENTAL FINDINGS



During Pharaon pilots, incidental findings must be appropriately analysed to determine whether it may cause some negative issue for the person involved. If need be, the analysis may need to involve an appropriate care professional such as a psychologist. The participant must know about the finding and his opinion must be considered. Depending on the case, the Pharaon pilot site coordinator must guarantee that all the ethical steps and prescribed legislation is followed. Each of these steps should be justified, not only with reference to costs and/or logistical considerations, but also with reference to moral obligations and the principle of reciprocity (BUNNIK, 2017).

GDPR



Detailed information is provided in D10.5. But a good checklist is available in: <https://gdpr.eu/checklist/>

MEASURES FOR THE PILOT SITES

GENDER



Three measures were proposed to approach gender issues in the project:

1. Use structures models such as the Unified Theory of Acceptance and Use of Technology (UTAUT¹), integrated with a RinG analysis².
2. Make a hands-on periodic review of all activities that will be undertaken, to identify possible gender biases emerging. The tool below is a potential guidance.
Also the following links may be of help:
<https://www.genderingermandevelopment.net/custom/images/contentBilderGalerie/bilderGalerie1000502/Giz-Gender-sensitive-project-management-2017-EN.pdf>
<https://www.civicus.org/documents/toolkits/guidelines%20for%20gender%20mainstreaming%20in%20project%20stages.pdf>
3. Depending on these periodic feedbacks, short training offers may be recommended to WP9 task leaders to ensure compliance with best practices.

GENDER MANIFESTO OF PHARAON

- The consortium will keep gender balance when selecting participants for co-creation activities and validation.
- Evaluation of all the tools will also focus on occurring gender issues.
- Representative data collection will ensure sex/gender specific.
- It will promote non-sexist language in the documentation generated during the project, especially within the interventions documents and in the dissemination materials.
- Although not directly connected to project implementation, gender balance in consortium will also have an impact thus, participation of both sexes in the work teams is encouraged.
- Any potential gender issues are not foreseen as gender distribution and participation is anticipated according to the normal distribution of sexes at the trial sites.
- Gender equality is based on equal treatment and opportunities as defined by the European and UN Policies (e.g. Council Directive 75/117/EEC) and is adapted by the members of this consortium.

¹ http://www.vvenkatesh.com/wp-content/uploads/dlm_uploads/2016/01/2016_JAIS_Venkatesh-et-al.-UTAUT.pdf

² <https://www.ringsgenderresearch.org/>

CHECKLIST FOR GENDER ANALYSIS:

PROJECT STAGE	GENDER ANALYSIS
Identification	• What are the objectives of the project? • Who are the target beneficiaries? • Can a gender-inclusive design be drawn up for the activities/pilots? • What is the gender balance in the target public ? • Is the project likely to have same positive and negative effects on women and on men? • Might the project, in general, reduce women's access to or control of some resources or benefits they currently have? • What social, economic and political effects will the project have on women and on men in the short term? In the longer term?
Design and Planning	Define objectives in terms of outputs and deliverables • Are project objectives clearly related to practical and strategic gender needs? • Have both men and women participated in setting those objectives? • Do women and men view the planned activity in the same way? Policy issues • How will men and women participate in the project, and in what capacities? • Are the regulatory policies that will affect what can or cannot be done in the project and/or how it must done?
Project Implementation	How will the following be achieved and who will be responsible for each area? • Staffing: scheduling, procedures, training, • Managing: organisational structures, on-site work • Logistics and operations, ordering and delivery of necessary materials How will various aspects of the project be co-ordinated? And by whom? • Are there appropriate opportunities for both women and men to participate in project management positions? • Are there mechanisms to ensure that the project resources or benefits are not controlled or taken over by one gender? Or by sub-groups, factions or individuals within / outside the community? How will disagreements and disputes be handled and by whom? Is every person on the project trained in gender-mainstreaming? If not, will this happen before activity begins?
Evaluation and Monitoring	Are there separate indicators to measure progress in achieving benefits for women and men?

SAFETY



One of the measures that Pharaon will have transversally throughout the project is the collection of good practices and materials connected to safety, that will then be distributed to all concerned partners and, when applicable or wished, adapted and translated to the different pilot sites.

As one example, the [Manual of Good Practices for Fall Prevention](#), developed by CDC/UC is an explanatory guide with the main causes of falls among older adults and that provides simple and clear guidelines and solutions to mitigate / avoid risks, both to the older adults as to caregivers.

Another aspect connected to safety is the one related to digital tools – examples of [ergonomic tips](#), [challenges](#) to overcome and [advice](#) on online safety for older adults.

VULNERABILITY



In this perspective, in Pharaon, although in principle all participating older adults are capable and without any major cognitive or physical impairments, the pilot sites coordinators will be advised to carefully assess the vulnerability framework of each participant in the project. D10.5 will provide possible methods for that evaluation and, if necessary, short term training sessions will be provided to ensure adequate application of the methods and tools.

CONSENT



In Pharaon, to ensure full compliance, the Ethics Manager provides to pilot sites an Informed Consent (IC) package, with the IC form, a factsheet and a revocation form to be used in the different phases of the project. In M5, the template provided was referring to the co-creation phases and tailored forms will be made available for the validation and piloting phases.

Pharaon's Ethics Manager provides to all pilot sites an Informed Consent (IC) package, with:

- Factsheet
- IC form
- Revocation form
- Procedures to collect IC

In M5, the templates provided referred to the co-creation phase, but tailored forms will be made available for the validation and piloting phases.

DIGITAL LITERACY



Digital literacy is a challenge that Pharaon will address, either through complementary training sessions for participants, as well as providing pilot organisations with guidelines and materials that can support them in tackling these challenges. Also, the Ethics Board will provide recommendations to the Technical partners for the development and integration, aiming to guarantee there is a specific caution in these areas of work.

DIGITAL ACCESS



Ensuring full digital access, as a human right that allows the accomplishment of other fundamental rights, and promotes sustainable development and improvement of quality of life, is one of the goals of the Pharaon project. Pharaon will aim at facilitating end users' full access, also considering specific measures that may promote the participation of more vulnerable publics, e.g. by providing the equipment, internet access, etc.

TECHNICAL MEASURES

1. ETHICS AS A FRAMEWORK

Ethics is a daily pervasive aspect of technologies, present in its different contexts. However, technical development is many times siloed and separated by components to which each person devotes too, often missing the final societal goal to which it is aimed. This often favours a tendency to sideline the ethical mindset and think of it as an external constraint rather than an integral part of common good. It is important that different works in technical tasks within the Pharaon project have the knowledge of the final purpose of their work, so they can fully understand the consequences of their choices.

2. LEGAL BEHAVIOUR IS NOT ENOUGH

Law and ethics are not the same. Many times, legal actions can be unethical and, although not so commonly, an ethical activity may be not completely framed within legality. Ethical compliance shall not be seen by Pharaon's technical partners as a box to check and tick and then forget about, as this can lead to unwanted consequences and make the project fail to deliver its vision and goals: to provide support for Europe's ageing population by integrating digital services, devices, and tools into open platforms that can be readily deployed while maintaining the dignity of older adults and enhancing their independence, safety, and capabilities. Pharaon partners shall assess the teleology and ethical purpose and not only the legality of their technologies and activities.

3. HUMAN LIVES BEHIND TECH

Technological solutions in Pharaon are used for important human interests and purposes, influencing human beings' lives, e.g. in health and care, emotional and mental states, physical aid, among others. Tech partners shall consider that ethical duties apply when developing technologies that touch these and other important aspects of people's lives. Thus, having a deep knowledge of all the different country scenarios and disclosing any doubts directly with pilot partners colleagues may help to have this into consideration in a more profound way.

4. ADDITIONAL RISKS FOR TECHNOLOGIES

Ethical issues concerning technology do not disappear after a first preliminary check. This is a dynamic pathway and multiple uses (many unexpected uses) can take place in pilot sites, by older adults, once devices, software, hardware, or data leave the hands of the technical partners. Extensive testing of a product before its release is essential but new applications might create new challenges. Thus, it is quite relevant that technical partners in Pharaon consider a view of the risks downstream from their practice, maintaining an effective communication with pilot sites to understand how their devices and software is being used in place.

5. AVOID ISLANDS OF KNOWLEDGE

Very often, there is a miscommunication between tech and non-tech partners in project, mostly due to different languages and different mindsets. Different levels of technical expertise will always exist, but Pharaon shall take different measures to tackle this dangerously insular mindset when it comes to considering the interests of non-technical actors and risks to which they are exposed, as this leads to missed opportunities to implement basic risk prevention and mitigation strategies, increasing the overall risk to the partners and their main target audience, the older adults.

Maintaining appropriate empathy between different partners is important and this requests for shared working spaces – tech partners need to present their devices and solutions to non-technical actors so that these can

understand at least their basic language; pilot partners and end-user representatives in Pharaon shall also make presentations of their sites and periodic results, so that the technical partners can understand how their solutions are being applied and better understand any issues that may need to be addressed.

6. ENVISION THE ECOSYSTEM

The technological solutions in Pharaon won't be working as a single product but, instead, their main aim is to be integrated, adapted and tested in different ecosystems, as a method for larger uptake. Thus, it is necessary to consider the full context in which the technology will be applied and for what purpose, the cultural context, expectations, values, and priorities of each setting. Ethical practices and obligations shall therefore be considered in light of this bigger picture and for this purpose, Pharaon MB shall provide to all partners a very clear and updated vision and status quo of the ecosystems, so that all possible interconnections and challenges are duly assessed in a timely manner.

7. MIND THE GAP ON USER EXPECTATIONS

Users usually expect that the technology being developed in a project reaches them already in a very mature state and that it will fully comply what they presented as needs and requirements in the co-creation phase. Often this happens also due to lack of knowledge and digital literacy of the older adults and technical partners shall consider that they in fact operate from a position of epistemic advantage and that only if their solutions are duly explained to the pilot partners in Pharaon, can then they also duly explain it to users. Good and basic manuals, with lay language and simple concepts for all the solutions are essential to this and shall be made available by all tech partners in Pharaon.

8. CHAIN OF ETHICAL ACCOUNTABILITY

As referred in previous points, technology is often developed in parts and pieces and then assembled to be delivered, which makes it quite difficult to have a responsible practice and accountability. Tech partners in Pharaon are recommended to create clear chains of responsibility and make them transparent and public, inside their teams, at early stages of the project, to avoid a diffusion of responsibility where no members of the team feel empowered or obligated to take the steps necessary to ensure effective and ethical practice. Each aspect of ethical risk management and prevention of harm must be detailed and clearly assigned, in each of the relevant areas of activity.

9. CRISIS SIMULATIONS

Usually, the potential effects of a solution are studied within the scenario predicted to its use. However, it is difficult to guarantee an effective crisis response if no worst-case-scenarios have been planned. Tech partners in Pharaon are urged to understand how their product or system will work in non-ideal conditions, or even outside the boundaries of its intended use, and thus build crisis management with appropriate margins of safety, also planning preventive and mitigation measures.

10. PRIVACY AND SECURITY BY DESIGN

Pharaon predicts from its creation that not only technical design (of networks, databases, devices, platforms, websites, tools, or apps), but also social and organizational design (of groups, policies, procedures, incentives, resource allocations, and techniques) is conceived in a way that promotes privacy and security objectives. This "grand" framework value must be known and made clear to all the workers in the partners teams of the project, as it frames most of the decisions to be done within the technological area and in the concept of each pilot site plan of activities.

ORGANIZATIONAL MEASURES

1. Pharaon's main statements

- a. Values declaration - defining general principles of the adequate behaviour to be undertaken during Pharaon's implementation. They shall represent the standards against which decisions and actions are evaluated to determine if they meet the project's expectations and requirements.
- b. Pharaon's Vision declaration - defining the long-term, desirable future statement for the project's implementation and uptake, that needs to be taken into account when setting performance goals for the different actions.

2. Pharaon's Ethics guidelines

The "code of ethics" defined in T10.5 shall provide the project's specific definitions of what will be expected and required in this field, during Pharaon's implementation, as well as the consequences for the failures to meet the expected standard. E.g. if a pilot site as not yet received a mandatory approval from the Ethics Committee, trial sites cannot begin.

3. Ethics communication strategy

Ensures that partners have the information they need in a timely and usable fashion and that the Pharaon is encouraging partner communication regarding the values, standards and the conduct of the project and its members in alignment with the guidelines proposed.

4. Ethics training

To partners if and whenever necessary, either informing them on the guidelines and relevant information, as well as hands-on?, providing them the opportunity to apply those guidelines in the real project settings and scenarios.

5. Ethics board

Oversees the organization's ethics initiative and supervises the ethics managers, being the final interpreter of the ethics code and the final authority on the need for new or revised policies and measures. Early in the project's timeline, it also acted as an ethics task force, creating the infrastructure that will now oversee. It is also responsible for initiating the Pharaon's response in any needs of review of the goal-setting guidelines and a test of the reasonableness of current goals.

6. Ethics manager

Pharaon ensures a project Ethics Manager as well as pilot sites Ethics Managers, who are all members of the project Ethics Board. These managers ensure that Ethics guidelines are in place and being implemented, monitoring, at the different levels, if the stated values, the code of conduct and the established measures are well understood and sufficient and any violations of those values are prevented or detected and addressed. The Ethics Manager also oversees the ethics communication strategy and mechanisms for the different partners to obtain guidance and report.

7. Ethics helpdesk

Provide a support email for all partners (Ethics Board Chair) and the emails of all Ethics managers in the pilot sites helps guaranteeing that any doubts can be easily answered, relevant information is provided and any unethical conduct timely reported. They also make it easier for Pharaon to provide guidance and interpretation of its expectations when the intent of an ethics policy is unclear.

6. Monitoring and periodic

Assess periodically the effectiveness of the ethics program in Pharaon and the extent to which partners accept and internalize the project's values and ethics code. With periodic ethical evaluations the pressure to comply is maintained, preventing failures and doubts.

7. Ethics leadership

The Coordinator, the Management Board, besides the Ethical Managers and Board needs to set the tone, shape the climate and define the standards, showing that Pharaon solutions and activities are trustworthy and trusted, with honourable motivations and clear expectations. This will ensure Ethics is high in Pharaon's agenda and that will inspire all partners to follow the guidelines and values established.



TOOLS

USER TIPS	21
MATRIX FOR USE CASES	22
INFORMED CONSENT PACKAGE	27
PROCEDURES TO OBTAIN INFORMED CONSENT	34
ETHICS DIALOGUE ASSESSMENT	36



END USERS RIGHTS

[TIPS]

Don't hesitate, if you have questions, go and talk with your caregivers or with the responsible research.
We are here to help you!



If you are no longer comfortable with the investigation, you can quit at any time! Don't worry, it won't have any consequences for you.



Feel free to involve (or not) the ones you want to be part of the process!



We are promoting a secure system, so your data is safe with us!



MATRIX FOR USE CASES

Recommendations	Use case scenarios / services developed					
	Scenario/case 1	Check	Scenario/case 2	Check	Blocking Y/N	Degree
1 - To respect users will in acceptable ethical standards, the Pharaon system should only work when required. For example:						
a) The user should be able to put the system in stand-by mode when it is disturbing the person or when it is suggesting an action that the user doesn't want. In the stand-by mode it should be possible to ask for help, for example when the older adult falls;						
b) It should be possible for the user not to allow the system to alert him when other people are present and he/she doesn't want to share certain types of information;						
2 - Even if the analysis of the state of art leads to the conclusion that it is not possible to settle all dilemmas, it is however important to safeguard some situations that collide with ethical principles, namely:						
a) The Pharaon system must be safe in terms of mechanical operation as well as in software. Depending on the tasks that it is enabled or scheduled to run, it must follow them precisely in order to reduce margins of error and incorrect decisions.						

Recommendations	Use case scenarios / services developed					
	Scenario/case 1	Check	Scenario/case 2	Check	Blocking Y/N	Degree
b) The use these technologies can collide with the professional activity health and care professionals, so it is important to explain that they aim to be an extension of the assistance provided to the older adults, allowing caregivers a better follow-up and monitoring, which in the end will result into a more solid support, an easier contact in case of danger or loneliness, but also in better information provided to the caregiver so that he/she can work in an even more professional way and directed to the person needs.						
c) Prior to the introduction of the technologies, there must be a risk assessment for the older adults, caregivers, digital tools and the environment. This risk evaluation should include assessment decisions as well as incorrect or improper actions; it should be possible to audit the system.						
d) Both Instructions as user manuals must be very clear and explicit so that users can operate any tools safely, understand how they work and parameterize them according to their will. The information about manufacturer, as well as standard regulations and certifications relating to their construction, recognized by authorities or independent entities, must be displayed.						
e) There should be liability insurance covering any damage caused to people, objects or buildings.						
3 - It will also be crucial to safeguard privacy and data protection. SO it is recommended that:						

Recommendations	Use case scenarios / services developed					
	Scenario/case 1	Check	Scenario/case 2	Check	Blocking Y/N	Degree
a) Data will be processed by the entities which collect information according to a pre-established methodology, and ab initio, anonymization of respondents must be assured. The results of this treatment should serve solely and exclusively for the purpose of the project and can only be made public in general terms to justify eventual technical choices.						
b) Data on personal life may require prior authorization by national authorities of the respective countries (e.g. National Commission This requirement must be fulfilled, ensuring transparency, clearly defined procedures and also accountability of those involved, if any problems occur.						
c) Regardless of data collection being manual or automatic, it must be possible for users to query their own data, as well as modify or eliminate them.						
d) It is also important to clarify the interaction human-machine with the cloud, anticipating potential risks and how to control or neutralize in crisis situations.						
e) In regard to the accountability of automated data collection, it should be possible to identify the origin of the collection so that it is easy to detect the origin of any malfunctions.						
f) As for the automatic processing of data, in case of an algorithm or set of algorithms, the tech providers are responsible to develop and implement security mechanisms to act quickly in case of crisis and to ensure self-protection redundancy, perform monitoring routines and system analysis, including intrusion attempts, of programming code changes or data theft.						

Recommendations	Use case scenarios / services developed					
	Scenario/case 1	Check	Scenario/case 2	Check	Blocking Y/N	Degree
g) In the security plan there must be persons designated for auditing the overall operation of the system. In this way it should be possible to ensure the supervision of compliance with legal and ethical standards, avoiding “grey areas” of responsibility.						
4 - Taking particular note of the GDPR, the following recommendations should be taken into account when implementing a protection system and data security (broad sense):						
a) Consent - a legible and understandable form to provide data processing consent must be prepared and shall contain:						
I. The identity and contact of the controller;						
II. A rigorous and comprehensive description of the object of consent;						
II. A rigorous and comprehensive description of the object of consent;						
III. The specific scope / purpose of the processing;						
IV. The consequences of providing consent;						
V. The right to revoke consent at any time;						
VI. The right to obtain information about their data.						
b) Those responsible for processing the data - Definition and identification of those responsible for data processing, which should determine:						

Recommendations	Use case scenarios / services developed					
	Scenario/case 1	Check	Scenario/case 2	Check	Blocking Y/N	Degree
I. The purpose, legitimacy, relevance and adequacy of the data to be processed;						
II. The need for regular monitoring of data accuracy and updating						
III. How the data will be processed;						
IV. The time limitation provided for storage of personal data;						
V. How the responsible will inform the persons concerned on the way to how their data is being processed;						
VI. In the case of joint responsibility for the processing, the specific purposes of the processing by each of the stakeholders must be established.						
c) Data security protocol						
I. Assess the appropriateness of proceeding to the anonymization of data						
II. The mechanisms that will be adopted to ensure the protection of data must be set in advance, e.g., by conducting audits; the delimitation of stakeholders with access to data; the development of workflows validations / approvals held.						

INFORMED CONSENT PACKAGE

FACTSHEET



Pilots for Healthy & Active Ageing

www.pharaon.eu



PILOT INFORMATIONS		
Country/Region		
Coordinator		
Partners involved in the pilot		
OTHER RELEVANT CONTACTS IN OUR PILOT SITE		
Operational Coordinator		
Technical Manager		
Social Manager		
Clinical Manager		
Cybersecurity Manager		
Data Manager		
Training Manager		
Ethics Board		

In Europe's rapidly ageing society, there is a growing need for tools that will improve the quality of life, independence and overall health of older adults. Advanced ICT solutions that combine technologies from multiple disciplines can address this problem, but the market is fragmented and many solutions have limited scope.

Pharaon's integrated platforms will be validated in two stages: pre-validation and large-scale pilots (LSPs), in six different pilot sites: Murcia and Andalusia (Spain), Portugal, The Netherlands, Slovenia and Italy. A set of development tools will be created and made publicly available to simplify the customisation and integration. These tools and the results of dissemination will spread the generated knowledge to promote the development of new solutions similar to Pharaon.

- IDENTIFY the current state of interoperability between widely used platforms and partner solutions and solutions from third parties involved.
- IMPLEMENT personalised analytics that provide older adults and their caregivers with the most pertinent physical and mental health as well as wellbeing information.
- DEMONSTRATE the feasibility of integrating the Pharaon platforms with existing systems related to intelligent transport and mobility, energy optimisation, and smart cities.
- ENSURE user-friendly human-computer interaction modes that address various capacity limitations and provide rapid access to useable information.
- VALIDATE the Pharaon platforms at an early stage providing feedback to the function and usefulness of these platforms and their integrated technologies.
- INVOLVE new stakeholders and their technologies, products, or services in the different ecosystems through the launch of open calls.



Programme
Horizon 2020
DT-TDS01-2019
Innovation Action (IA)

Grant ID
857188

Coordinator
Sant'Anna School of Advanced
Studies - Pisa

-  www.pharaon.eu
-  contact@pharaon.eu
-  [@PharaonProject](https://twitter.com/PharaonProject)
-  fb.me/pharaon.project
-  [Pharaon Project](#)
-  [Pharaon - Pilots for Healthy and Active Ageing](#)



INFORMED CONSENT FORM

Information folder for participation in project Pharaon.

Dear Sir / Madam,

You have been invited to take part in this evaluation study which is part of a European research project which main objective is to integrate digital services, devices, and tools into open platforms that can be readily deployed while maintaining the dignity of older adults and enhancing their independence, safety, and capabilities. You will receive detailed information about this study in a personalized way.

This information folder has two parts:

- Part I: General information about the study
- Part II: Informed Consent [to be signed if you agree to participate in the study]

If you do not want to participate, this will not affect your relationship with the organisation in any way, and there will be no negative consequences for you. If you agree to participate, you are also free to leave the study at any time, without the need of further justification. Your choices and your rights will always be respected.

The engagement of people in research projects is essential to deliver useful and relevant results. In order to do so, we need you to provide your written consent to cooperate with us. Please read carefully the Part I of this information folder before making a decision. You can also ask for the clarifications you need and ask any question that does not have a clear and complete answer in this document.

Sign **Part II** of the information folder only if:

- You fully understood the type and procedure of the evaluation study.
- You are willing to give your consent in writing.
- You understand your rights as a participant in this research project.

PART I: GENERAL INFORMATION

1. What is the purpose of this evaluation study?

This evaluation study is part of the activities of the research project – Pharaon, cofunded by the European Commission in the Horizon2020 funding programme [Grant Agreement number 857188].

The overall objective of the Pharaon project is to support Europe's ageing population by integrating digital services, devices, and tools into open platforms that can provide personalised and optimised health care delivery.

Pharaon's integrated platforms will be validated in two stages (pre-validation and large-scale pilots [LSPs]), in six different pilot sites:

- Murcia [Spain]
- Andalusia [Spain]
- Portugal [Coimbra / Amadora]
- The Netherlands
- Slovenia
- Italy [Tuscany / Apulia]

The purpose of this study is to:

- i) IDENTIFY the current state of interaction between used systems in each pilot site and partner solutions
- ii) IMPLEMENT personalised analytics that provide older adults and their caregivers with physical, mental

health and wellbeing information.

iii) DEMONSTRATE the feasibility of integrating the Pharaon platforms with existing systems related to transport and mobility, energy optimisation, and smart cities.

iv) ENSURE user-friendly interaction with the different technologies provided.

v) VALIDATE Pharaon platforms at early stage providing feedback to their optimisation.

2. Who is the responsible for the study in [FILL pilot site]?

The project has the participation of [FILL Institution name].

[FILL Institution name] is the responsible for the activities in [FILL pilot site].

All contacts are available below in section 10 of this document.

3. How will this study work?

Co-creation phase

We wish to collect your needs and wishes to ensure that the results of the project will be of interest to older adults and their caregivers.

[FILL number] participants will be involved in [FILL name of pilot site] through [FILL group sessions, individual interviews, phone calls, telco].

If you agree to participate in the study, we will make an appointment with you. This is expected to take between [FILL hours/min].

The interview questions will focus on your personal opinions on different aspects.

Before signing, please bear in mind that, due to the Covid-19 pandemic and emergency state restrictions, in the case of a telephone or other remote interview, your consent may be recorded using a voice recorder in a preliminary phase. This recording will only be kept until this consent form is duly signed and destroyed just after.

The questions and answers may also be recorded so that the researchers can go back to what was said during the interview later on. In this case, the interview data will be transcribed (written down), translated into English and analyzed. All personal information that could lead to your identification will be done in a separated recording, so that there is no connection between your answers and your identification. All the answers to the questions are only analysed, treated and shared in a completely anonimised manner.

4. What are the benefits of your participation in the study?

By participating in this study, and providing your opinions, you are contributing to the development of a system of services that aims to support you as you age.

It is possible that your participation in this study will not directly benefit your health; however, by participating and providing us with your feedback, you will contribute to develop an efficient and practical multifunctional support system for older adults. The results of this evaluation will allow us to better define the system to be developed so that the Pharaon solutions are useful and adequate for you and other older adults.

5. Are there any risks, discomforts or side effects related to your participation in this study?

Since it is a non-invasive study, no significant risk is predicted. However, if you find any doubt, difficulty or problem, immediately contact the Main Researcher for the study in [describe pilot site].

6. Is there any cost involved in participating in the study? Is there any financial reimbursement for participants?

Absolutely no costs or any other financial consequences will arise for you as a participant of this study. Participants will not receive any financial compensation for participating in the study.

7. Data Protection

In what way will the collected data be used?

All data will be protected against unauthorised access. The data collected about you will be safely stored by [FILL institution and country], completely separated from this consent form and your name.

Only completely anonimised data will be shared with other consortium partners (all inside the European Union) for aggregated analysis. This means that your name will not be used in connection with any of the data collected and there will be no link between your answers and your personal information. In this way, it will not be possible for any other researcher to identify what were your responses.

Any data shared with other researchers and research institutions that are not part of the consortium will be completely anonymised as well. Likewise, any publications that may result from this study will not include any personal data that may lead to your identification.

You can oppose your consent to the processing of your data at any time. After this decision no further data will be processed.

The research team involved in this study ensures that the resulting material will be stored in a safe, anonymized location no later than [FILL] years after the completion of the study. All members of this study are bound and guided by European data protection standards (GDPR).

If you have any questions about the processing of your personal data, please contact the [FILL person in charge of data processing of this institution].

8. Early withdrawal of your participation in the study

You can interrupt your participation at any time without any explanation. The withdrawal will have absolutely no negative consequences for you at [FILL institution].

Even after completing the study, you have the right to express your wish that your data be removed and deleted, except for those that have already been published or used in reports that cannot be redeemed or changed. To request the deletion of your data, please contact the investigator in charge of the project.

To interrupt your participation in the project or request the deletion of your data, please contact the project manager, by phone or email. You can find the contacts at the end of this document.

9. Possibility to discuss other issues

If you have any questions about the project or about your participation in it, you can contact the Main Researcher at [FILL institution] (see contact details below) now or later.

You can also contact the Coordinator of the project, responsible at international level – [FILL name, institution, place, email address]. In addition to the researcher responsible for the study and the person in charge of the data processing from [pilot sites], you have the right to complain to the [FILL country] National Data Protection Commission about the processing of your personal data through [FILL e-mail, telephone].

10. Contacts

Main Researcher responsible for the study at [Institution name]

Name – [FILL]

Contacts – [FILL telephone number | [email]

Data Protection Officer at [Institution name]

Name – [FILL]

Contacts – [FILL telephone number | [email]

Project Coordinator at international level

Name - [FILL name, institution, place, email address, telephone]

If you wish to participate in this study Pharaon, we would like you to complete Part II – Informed Consent Statement and to keep this information folder.

PART II: INFORMED CONSENT STATEMENT

I have been thoroughly and comprehensively informed about the objective, the meaning and the scope of the Pharaon [FILL chose co-creation/preevaluation/ evaluation trial] and about any resulting requirements as well as any potential risks and possible impacts to myself and my life. This information was given

by Mr /Mrs _____. I have read/it has been read to me [strike out what does not apply] the above [FILL] pages of information. I have had the opportunity to ask questions about it, and any questions that I have asked have been answered to my satisfaction. Consequently, I am able to confirm that I have understood the provided information.

I will adhere to any requirements that are necessary for the implementation of the study, while reserving the right to withdraw my voluntary participation at any given time, with no negative consequences implicated to myself.

I consent voluntarily to participate in this research project:

- ☐ I declare my consent to take part in this study.
- ☐ I declare my consent to recording (including interview voice recording and transcription), transfer and storage of my personal data as described in chapters 3 and 7.
- ☐ I declare my consent to the sharing of completely anonymized data with organizations outside the Pharaon project for the established period of time.

Name of the participant: _____

ID number: _____

Identification Code: _____

I have received a copy of this patient participation informed consent form. The original form will be stored at the care service provider.

Signature of participant: _____

Day/month/year: _____

TO BE COMPLETED BY THE RESPONSIBLE OF THE STUDY IN THE ORGANISATION

I, _____ declare that the participant spontaneously signed and agreed to his participation in this study.

I also declare that:

- ☐ I provided the participant with all the necessary information for the understanding of this study, its purposes, procedures, possible risks and benefits.
- ☐ I confirmed that the participant understood the provided information.
- ☐ I provided time for reflection and the opportunity to ask questions about the study.
- ☐ I have not exercised any coercion or otherwise influenced his/her consent.

Signature: _____

Date: ____ / ____ / ____

REVOCATION SHEET

To be used only in case you wish to leave the Pharaon study.

PART III: REVOCATION OF CONSENT

Dear Sir / Madam,

You have been invited to take part in the Pharaon study, which is part of a European research project with the main objective of integrating digital services, devices, and tools into open platforms that can be readily deployed while maintaining the dignity of older adults and enhancing their independence, safety, and capabilities.

However, you withhold the right to interrupt your participation at any time, without having to provide particular explanation, and not being subject to any negative associated consequences for you at _____
[FILL institution]. In case you intend to exercise that right, please fill with your data below, if possible, in your own handwriting.

I, Mr./Mrs [strike out what does not apply] _____, with the ID number _____,
REVOKE the consent previously given for the inclusion of my data in the Pharaon research study, without having received any kind of opposition or undesirable consequences.

[INSERT location and date]

_____, ____ of _____ of 20____.

[If possible, please sign in your own handwriting]

The participant: _____

PROCEDURES TO OBTAIN INFORMED CONSENT

METHODS TO OBTAIN CONSENT



Whatever method is used to collect consent, there must be an unambiguous indication by clear affirmative action. Recital 32 of the General Data Protection Regulation (GDPR), that clarifies [article 4 GDPR \(Definitions\)](#) and [article 7 GDPR \(Conditions for consent\)](#) states:

*“Consent should be given by a clear affirmative act establishing a freely given, specific, informed and unambiguous indication of the data subject’s agreement to the processing of personal data relating to him or her, such as by a written statement, including by electronic means, **or an oral statement**. This could include ticking a box when visiting an internet website, choosing technical settings for information society services or another statement or conduct which clearly indicates in this context the data subject’s acceptance of the proposed processing of his or her personal data. Silence, pre-ticked boxes or inactivity should not therefore constitute consent. Consent should cover all processing activities carried out for the same purpose or purposes. When the processing has multiple purposes, consent should be given for all of them. If the data subject’s consent is to be given following a request by electronic means, the request must be clear, concise and not unnecessarily disruptive to the use of the service for which it is provided.”*

This means that there is the need to ask participants to actively opt in. An active opt-in mechanism may include:

- **answering yes to a clear oral consent request;**

Silence, inactivity, pre-ticked boxes, opt-out boxes, default settings or a blanket acceptance of our terms and conditions are not acceptable.

If there are various different purposes or types of processing, consent is needed to all separately with a clear yes for each. Participants should not be forced to agree to all or none.

HOW TO RECORD CONSENT?



Article 7 of the GDPR states:

“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.”

This means we must be able to provide evidence of an effective audit trail regarding how and when consent was given. Keeping the audio record is mandatory and should include:

- **Who consented:** the name of the participant.
- **When they consented:** online recording that include a timestamp or a note of the time and date which was made at the time of the conversation.
- **What they were told at the time:** records should include a copy of the script used at that time.
- **How they consented:** provided through the recording made at the time of the conversation - it doesn't need to be a full record of the conversation, just of the consent part.
- **Whether they have withdrawn consent:** and if so, when.

TELEPHONE OR ONLINE CALLS



When pursuing telephone or teleconference consent, in addition to the researcher, at least one other designated employee should be present on the telephone to witness the consent conversation and subsequently sign the applicable document. This second person can be absent from the questionnaire answers, only needs to be present for consent.

The conversation must begin by identifying and verifying the parties on the call and explain to the participant that another colleague is on the call to serve as a witness to the conversation.

Please clearly verify that the participant is legally capable and there is no need of a legal representative to make decisions on his/her behalf (who lacks decision-making capacity).

The researcher shall then obtain the informed consent. To the extent possible, she/he must provide the participant with the same information that would be provided in person, e.g., the same level of disclosure and an opportunity to discuss the information provided.

DOCUMENTATION



The researcher obtaining consent must document the following:

- the name of the participant from whom she/he obtained consent and the confirmation that the participant is legally capable
- the exact time of the conversation
- the name of the witness to the conversation
- the reason why the consent was obtained by telephone
- the elements of the consent conversation
- the participant's understanding and agreement to proceed
- all the separate options the participant opted-in (or did not), all separately addressed.

INFORMED CONSENT FORM



After the telephone discussion, the consent form must be either sent by post, faxed or mailed to the participant so that he/she can sign the consent form and return it prior to the procedure.

In the case this is not possible for quarantine reasons, the signature may be collected as soon as it is possible to reach the participant again. The form duly signed is always needed.

The researcher and the witness should sign, time and date the informed consent form when returned.

ETHICS DIALOGUE ASSESSMENT

ETHICAL DIALOGUE ASSESSMENT		
Dimension	Specific Challenge	Ethics Recommendations
External factors		
Internal factors		
User interaction		
Other		

Cáritas Coimbra - May, 2020

www.pharaon.eu
contact@pharaon.eu
[@PharaonProject](https://twitter.com/PharaonProject)
fb.me/pharaon.project
[Pharaon Project](https://www.youtube.com/watch?v=PharaonProject)
[Pharaon - Pilots for Healthy and Active Ageing](https://www.linkedin.com/company/pharaon-project)