



SHAPES

Smart and Healthy Ageing
through People Engaging in supporting Systems

D8.2 – Baseline for Project Ethics

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Lead author	Sari Sarlio-Siintola (LAUREA)
Contributors	Karoliina Nikula (LAUREA), Teija-Kaisa Aholaakko (LAUREA), Nina Alapuranen (LAUREA), Panos Kartsidis (AUTH), Ioanna Dratsiou (AUTH), Maria Metaxa (AUTH), Michael Scott (NHSCT)
Peer reviewers	María José Santofimia (UCLM), Ian Spero (AAA), Shirley Davey (ULS)
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Table of Contributors

Table 2 Deliverable Contributors

Section	Author(s)
1-7	LAUREA
2.5, 3.5	AUTH
1-7	NHSCT

Table of Acronyms and Abbreviations

Table 3 Acronyms and Abbreviations

Acronym	Full Term
ALLEA	All European Academies
CoC	Code of Conduct
DPIA	Data Protection and Privacy Impact Assessment
DPM	Data Protection Manager
EAB	Ethics Advisory Board
EM	Ethics Manager
ET	Ethics Team
GDPR	General Data Protection Regulation
IF	Incidental Findings
IPR	Intellectual Property Rights
PbD	Privacy by Design
R&D	Research and Development
SI	Sensitive Information

Keywords

ethics, research integrity, governance, guidelines, templates

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1 Introduction to the document

The ethical issues in the SHAPES project includes both SHAPES development work (process) and the defining and implementation of ethical requirements as features of the proposed SHAPES solution during that development and implementation work (outcome, solution to be created).

The purpose of this document is to serve as a baseline for the ethics in research within SHAPES and to state how ethics are managed within SHAPES: this means the processes, principles and pilots. The focus is on the general research integrity, ethics management and ethics governance model. Data management is excluded from this deliverable D8.2 and is discussed in Data Management Plan (D8.13). Ethical issues related to the features of the SHAPES solution (including, e.g., privacy and data protection functionalities, transparency of the AI algorithms) will be discussed in more detail in a separate document, Ethical Framework for SHAPES solution (D8.4).

The cornerstones of this deliverable D8.2 are congruent with the European Union Ethical guidelines (ALLEA 2017; Horizon 2020 instructions), European and national legislation of the SHAPES partners, professional codes of conduct and field-specific guidelines.

The starting point is to assume that each responsible researcher working within SHAPES is a professional researcher doing (applied) research that will serve as a tool for development work within SHAPES. This means that everyone doing research is already assumed to be aware of research integrity and research ethics; European ethics legislation and the ethical research conduct (see e.g. ALLEA (2017), Beauchamp and Childress (2013), Belmont Report (1978), EU Commission (2010), Newman & Brown (1996), European Commission (2013)). This document is to serve as a general baseline for research ethics in SHAPES and it will help the new researchers to be aware of the relevant information in the SHAPES context and to find the relevant sources for further reading. If additional research ethics education is needed, we may arrange further education, if decided within the consortium.

This document is structured so that first, in section 2, we discuss the ethical aspect of and ethics management in the SHAPES project, including general ethical principles to be applied. In section 3, we briefly discuss the main ethical challenges related to the SHAPES. Sections 4 and 5 focus, in more detail, on challenges related to the participation of humans and to incidental findings.

Work package leaders and principal researchers and experts in development and innovation are responsible for the implementation of relevant national legislation

regulating research as part of the SHAPES ethical baseline documentation in assistance to the templates constructed for practical work.

2 Ethical, legal and societal issues in the SHAPES project

2.1 Perspectives on ethics work in SHAPES

Ethical issues in the SHAPES project includes both SHAPES development work (process), as well as defining and implementation of ethical requirements as features of the proposed SHAPES solution during that development and implementation work (outcome, solution to be created).

By investigating ethical issues related to the process and to the solution, we are trying to make the ethics work more applicable from the viewpoint of researchers, technology developers, business and ecosystem modellers and other actors.

SHAPES pilots are multifaceted from the viewpoint of ethics, since they concern ethics of development work, validation of the ethical features of SHAPES and the use of SHAPES in real-time settings. In those pilots, we conduct a validation in an environment that expects the development version to be piloted itself, fulfilling the minimum legal requirements.

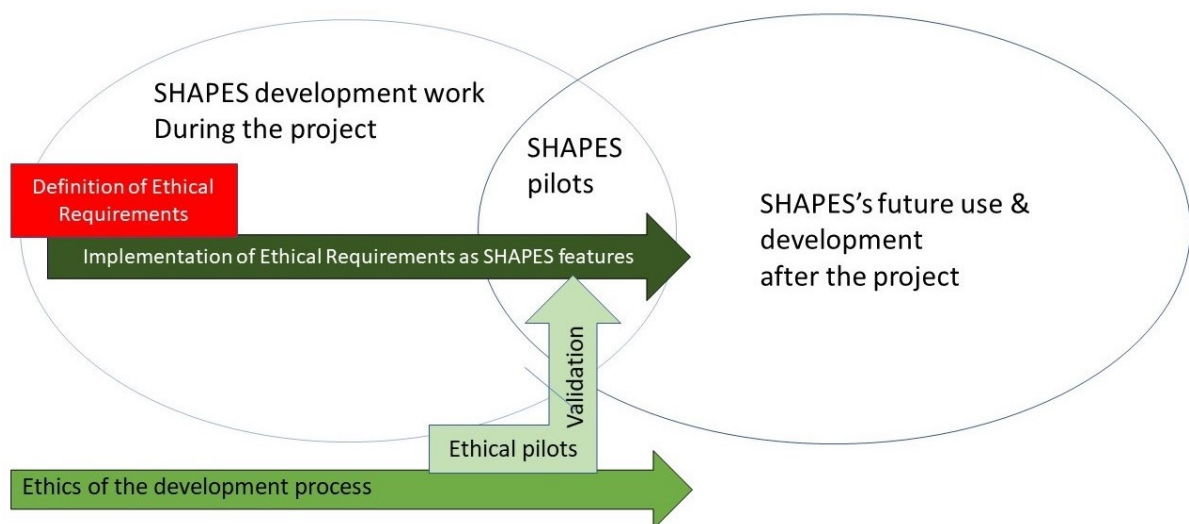


Figure 1: Ethical dimensions in the SHAPES project

2.2 Ethical deliverables for research integrity and for ethical SHAPES solution

This deliverable Baseline for Project Ethics (D8.2) focuses on the process and its management, including research integrity challenges relevant to SHAPES. In addition, general ethical principles and values that pose impact on both the process and

outcome are discussed in this deliverable. The deliverable Ethics Advisory Board (D8.1) complements this deliverable D8.2 by providing information both on the EAB process and the EAB members.

The document Ethical Framework for SHAPES solution (D8.4) in turn focuses on the SHAPES solution and its ethical dimensions. The same applies to the deliverables related to the Regulatory Frameworks (D8.3), Data protection (D8.11 and D8.12), and Ethical Risks Assessments (D8.8 and D8.9).

Finally, The Data Management Plan (D8.13) discusses both the management of the research data produced as part of the SHAPES process and data management of the SHAPES solution.

Table 4: Ethics deliverables for the SHAPES project

Deliverable	Timetable	Focus and Contents
Ethics Advisory Board D8.1	M4	Provides information on the EAB working practices, as well as on the composition of the EAB.
Baseline for Project Ethics D8.2	M6	Provides the guidelines and templates for research integrity and for the ethics management of the SHAPES project.
Ethical Framework for SHAPES solution D8.4	M7 and M18	Provides ethical and legal requirements for the SHAPES solution (technology and services, user processes and training, business/governance and ecosystem models). Legal frameworks for Smart and Healthy Ageing and for Privacy and Data Protection will be investigated in more detail later on in deliverables D8.3, D8.11 and D8.12.
SHAPES Data Management Plan 8.13	M6	Provides Data Management Plan for 1) SHAPES solution (data processed on the SHAPES platform) 2) SHAPES R&D process (research data collected and processed during the SHAPES project).
Regulatory Frameworks for Pan-European Smart and Healthy Ageing D8.3	M42	Elaborates on the legal frameworks identified earlier in D8.4 and analyses the extent to which current legal frameworks facilitate the creation of pan-European systems for healthy ageing.
SHAPES Privacy and Data Protection Legislation and Impact Assessment D8.11 and D8.12	M24 and M48	Elaborates on the privacy and data protection regulation (based on the initial requirements defined in D8.4) and provides Privacy and Data Protection Impact Assessments of the SHAPES solutions to be piloted.
Privacy and Ethical Risk Assessments D8.8 and D8.9	M12 and M24	Analyses risks and mitigation strategies and actions related to the ethical and privacy risks of the SHAPES solution (technology and services, user processes and training, business/governance and ecosystem models.)

2.3 The general value base

SHAPES focuses on the renewal of services providing assisted healthy ageing and fostering both dignity and independence according to the principles of autonomy and beneficence. Thus, the legitimacy of SHAPES solution is based on ethical and societal grounds, and its outcomes and future impacts must be justified ethically following the principle of justice.

The SHAPES process in turn is ethically laden, due to the fact that the development of the SHAPES solution is based on 1) research on older people's health and wellbeing, 2) active collaboration with various end-users and stakeholders and 3) large-scale pilots with end-users in real time settings.

The following aspects are embedded in the SHAPES development work and management to ensure the sustainability of such ethics (see also D8.4 about more detailed information about biomedical ethics, health care ethics, GDPR, EU fundamental rights and capabilities approach in the context of SHAPES solution):

- Issues of research integrity in the SHAPES project include the classical ethical principles of respect for persons, beneficence and justice, underlying the ethical conduct of biomedical and behavioural research involving human subjects in the Belmont Report, the National Commission (1978). The Belmont Report has introduced the three pillars of research integrity: selection of participants, Informed Consent and Risk-Benefit analysis.
- The SHAPES project respects European guidelines for Research Integrity; open-access publication; copyright and other potential IP rights; avoidance of plagiarism; respect of all stakeholders; cultural integrity; and sustainable use of natural and human resources (European Commission 2010) in abidance of "The European Code of Conduct for Research Integrity" by the All European Academies (ALLEA 2017). ALLEA recommendations propose a code for self-regulation in research for all scientific and scholarly fields. The code describes professional, legal and ethical responsibilities and acknowledges the responsibility of the research institution. It states the responsibility to educate personnel and students of research and development organisations in matters of research integrity and defines misconduct and other unacceptable practices in research. The responsible persons must be aware of how the evaluation context and selected methods affect the perceptions and behaviours of all stakeholders, researchers, developers and other participants and how their cultural background affects expectations and behaviour (Newman & Brown 1996, 171); see the table below.
- SHAPES has adopted the Responsible Research and Innovation (RRI) approach, which seeks to align technological innovation with broader social values and to support institutional decisions concerning the goals of research and innovation in conditions of uncertainty and ambiguity. The European Commission's RRI keys of ethics, societal engagement, gender equality, open access/science and science education are all essential, both from the viewpoint of the SHAPES R&D process and of final outcomes (SHAPES ecosystem of services).
- The SHAPES project and solution are both based on EU Fundamental Rights and on the Human Capabilities of the older persons to live full, good lives. This covers e.g., the rights to dignity and privacy and data protection, as well as the capabilities for practical reason, control over one's own environment, affiliation and senses, imagination and free thought. These rights and capabilities affect not only the collaboration with the older persons during the SHAPES project but also provide guidelines for the design of the final SHAPES solution and its digital service.

- Biomedical ethics is a contemporary, interdisciplinary, ethical approach based on four main principles: justice, beneficence, non-maleficence and autonomy. It serves a paradigm in assisting healthcare professionals and public policymakers in identifying and responding to moral dilemmas in healthcare and biomedical research (Beauchamp & Childress 2013; Kass 2001). In high-tech development and related research, the perspective of Biomedical ethics, its terminology and tools facilitate the construction of bridges between public healthcare, private healthcare, social services and engineering. They all focus on ethical and morally sound renewal of services provided to assist healthy ageing and foster dignity and independence, according to the main principles in Biomedical ethics, autonomy, justice, beneficence and harm avoidance. The biomedical ethics approach enhances the shared understanding of SHAPES participants by serving a model for ethical decision-making (Newman & Brown 1996). Biomedical ethics also provides practical tools for involving ageing people as experts-by-experience in transparent decision-making, facilitating their everyday lives (Pirhonen et al. 2018). Biomedical ethics are applicable when securing the autonomy of vulnerable groups (e.g., individuals with cognitive, sensory or motor impairments), in respecting the rights of culturally diverse participants and end-users, as well as in safeguarding the integrity of underage participants. These issues are relevant from both the viewpoint of SHAPES research and the development and use of certain SHAPES services dealing with health data.
- The Public Health paradigm protects and promotes health through societal, rather than individual, actions, thus improving wellbeing in societies by ensuring “societal conditions under which people can lead their lives”. The Public Health paradigm is implemented to advance individual liberties, further social justice and to identify and minimise the burdens of the projects on population and individuals. It also supports fair conduct of the projects and for determining which burdens are acceptable to the participating communities, as well as implementing the codes of ethics, including the “code of restraint, a code to preserve fairly and appropriately the negative rights of citizens to noninterference” (Kass 2001). The Public Health paradigm serves a population level view for the service development in the SHAPES project. Together with the Biomedical ethics, it enhances implementation of equity and principles of equality in individuals’ care. In addition, it can facilitate cost-effective use of services, simultaneously securing the integrity of its users. From the view of the Public Health paradigm, recognition, production and sharing of cross-sectional data is possible for use in enabling unbreakable service chains and cutting delays in interdisciplinary care.
- Legal and Regulatory Frameworks on Pan-European Smart Healthy Ageing (D8.3) investigates regulatory frameworks and identifies the extent to which the current legal framework facilitates the creation of pan-European systems for smart healthy ageing. The primary point of reference is the EU’s Patients’ Rights Directive, which pose an impact on the final SHAPES solution but also on circumstances in which the solution will be piloted.
- Privacy by Design (PbD) and General Data Protection Regulation (GDPR) compliance are the starting points for the design of technology, user processes

and governance, and the business model behind SHAPES. Special attention will be paid to integrity, availability and confidentiality and to challenges related to big data and artificial intelligence. In addition to the SHAPES solution, the GDPR affects SHAPES research and dissemination.

- In addition to above principles and regulations, both the research and development process and the pilots must follow national guidelines; e.g., in Finland it must adhere to the guidelines of the Finnish National Board on Research Integrity (TENK 2019) and relevant legislations. Each agent must sort out the local guidelines and regulations.
- WHO Guidelines, especially Global Age-friendly Cities (2007) is a relevant framework for age-friendly cities approach. WHO regards active ageing as a lifelong process shaped by several factors that, alone and acting together, favour health, participation and security in older adult life. Age-friendly cities and communities benefit all generations and strengthen the fabric of society as a whole. The World Health Organization has identified eight domains that make a community age-friendly. The domains are: 1) Outdoor spaces and buildings, 2) Transportation, 3) Housing, 4) Social participation 5) Respect and social inclusion, 6) Civic participation and employment, 7) Communication and information, 8) Community support and health services. (World Health Organization 2007).

2.4 The Ethics Governance Model

In order to properly address the ethical and social issues that have been described above, the SHAPES consortium has identified a dedicated work package within the project. While SHAPES researchers and developers notice ethical and social aspects in each of the projects' work packages and tasks, special attention is paid attention to work package WP8. The ethical governance model (based on systematic guidance, monitoring and reporting on the implementation of ethical requirements and guidelines), is embedded in the structure of WP8 (see picture below). From the viewpoint of ethics management, the key actors are the Ethics Manager (EM), Data Protection Manger (DPM) and the internal Ethics Team (ET) as part of Task 8.1. The role of the internal ethics team is to review deliverables from the ethics point of view, as well as provide ad hoc consultancy on ethical issues that emerge during the SHAPES project.

The Ethical Advisory Board (EAB) provides independent input to the Consortium on ethical compliance based on the reports and project meetings. Their comments will be included unabridged in the periodic ethics reports (see separate document D8.1).

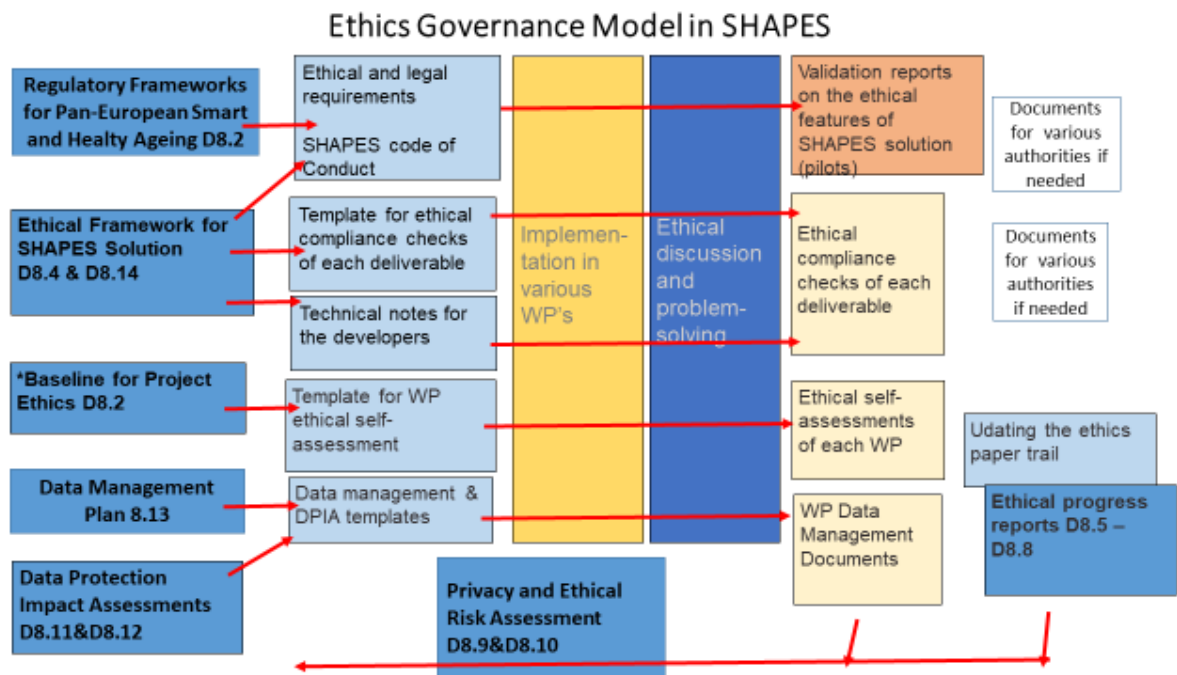


Figure 2: SHAPES Ethics Governance Model

2.4.1 Research integrity procedures

All the SHAPES project partners commit to upholding ethical research standards, including the European Code of Conduct for research integrity. They are committed to delivering high-quality scientific outputs and to be transparent, ensuring deliverables' reliability and impact. These features of deliverables are validated as part of the quality management procedures.

The principles of maximizing benefit and minimizing harm, social responsibility, dignity of persons, fundamental human rights and other issues mentioned in the Horizon 2020 ethical self-assessment are supported during the R&D work by taking into use ethical self-assessment procedure as part of the SHAPES governance structure (appendix 1). This ethical self-assessment is based on the Horizon 2020 template, but it is further modified for the specific purposes of the SHAPES ethics governance, including the activities discussed in section 3 and 4. The process is as follows:

1. Each WP leader provides ethical self-assessment (with necessary documents) of her/his WP and delivers it to the EM and uploads it to Teams. (see appendix 1).
2. If problems occur, they are to be discussed with the EM and in the EAB.
3. The EM will record the activities in the ethics paper trail and include it in the ethical progress report.

(Procedures regarding data management, see Data Management Plan (D8.13)).

2.4.2 Definition and implementation of ethical requirements as SHAPES features

The ethical requirements for the SHAPES solution will be defined in Ethical Framework for SHAPES solution (D8.4 and D8.14).

To ensure that the ethical requirements are mutually understood, carefully prioritized and successfully implemented, the following activities are needed:

1. First, WP leaders and task leaders familiarise themselves with the requirements by going through the list of ethical requirements defined in D8.4 and D8.14.
2. It is important to perceive whether we can accept differences (and mitigations) in the implementation of the requirements in the pilot version of the SHAPES solution, compared with the final version.
3. If clarification is needed, the EM and DPM are tasked with providing technical notes on the translation and implementation of the ethical requirements so that they can be taken into account in various tasks and deliverables. This work is carried out by providing needed documents and specifications and/or organising zoom-meetings.
4. Task leaders are expected to conduct an ethical compliance check of their deliverables as part of the research work (see appendix 2). In case clarification is needed about the requirements or if other ethical viewpoints emerge, the EM and DPM may be requested to provide help in the implementation of the ethical requirements.
5. The ethical compliance checks provided as an addendum to each deliverable are further reported in the ethics paper trail and ethical progress reports by the EM.

2.4.3 The pilots

2.4.3.1 Research integrity

The process regarding research integrity is based on Ethical Self-assessment described in sub-section 2.4.2.

1. Each pilot organisation provides ethical self-assessment with attached documents (see appendix 1) and delivers it to the EM and upload to teams. It is essential to follow local guidelines and regulations regarding various piloting activities with the citizens.
2. If problems occur, they are to be discussed with the EM and DPM.
3. The EM will record the activities in the ethics paper trail and submit it as part of the ethical progress report.

2.4.3.2 The validation/verification/assessment of ethical features of SHAPES

As the ethical requirements for the SHAPES solution (see D8.4) concern the SHAPES technology, its user processes and training, and future business/governance/ecosystem models, their verification/validation/assessment must be multifaceted.

1. Ethical requirements related to SHAPES technology and the use of it should be validated as part of the general SHAPES validation approach during the pilot phase. This includes not only ethical features of the various digital services and data analytics but also, e.g., validation of consent to be collected on the SHAPES platform.
2. Ethical requirements relating to privacy and data protection will be assessed as part of the SHAPES Privacy and Data Protection Impact Assessment (DPIA) (D8.10 and D11). Each pilot shall do a DPIA before the pilots start.
3. The ethical requirements related to the business and governance model may not necessary be validated as such during the project. On the other hand, by providing an ethics compliance check of each deliverable, it is possible to verify that the various ethical issues have been considered in various deliverables.
4. Feedback on the SHAPES Code of Conduct (see D8.4) will be collected via questionnaire from pilot participants.

The EM and DPM will provide specific technical notes on the validation/verification of ethical requirements before pilots.

2.4.3.3 Ensuring ethics compliance of the SHAPES version to be used in pilots

The minimum ethical requirements to be met by the pilot version of SHAPES itself concern legislation, namely data protection, IPRs and local data information sharing regulation, including use of secondary data sources.

Minimum ethical requirements (ethical requirements, see D8.4) concerning the pilots can be defined after the data sources are defined in the Data Management Plan (D8.13) and when the Privacy and Data Protection Impact Assessment (D8.10 and D8.11) are completed. For the sake of clarity, each pilot needs to have its own data management plan ready before the pilot starts. Technical notes will be provided for the work by the DPM.

(Procedures regarding the data management, see Data Management Plan (8.13)).

2.5 General ethical principles for management and research

The classical ethical principles introduced below serve as a basis for the selection of the SHAPES project's ethical principles and construction of the ethical statements guiding the research, development and innovation during the entire SHAPES project. These principles were selected for reviewing the morally sustainable progress in co-creation of outcomes and findings during the entire project. The principles and statements are binding to all stakeholders, even the most important roles such as managers, administrators, methodologists and reporters working in the SHAPES-project supported by the project coordinator, work package leaders and the external and internal ethical experts (Newman & Brown 1996, 5).

Research integrity and ethical issues are determining factors for the successful implementation of a project that involves users and especially trials in the health domain, such as SHAPES. When it comes to technology and data sharing in general, where personal data obtain a special meaning (ETSI TR 2005), a series of public issues may arise: the difficulty of ensuring privacy and confidentiality when third parties are interested in gaining access to stored personal health data, or the difficulty in assuring the security of shared personal data. On the other hand, some of these issues may arouse controversy; more specifically, effectiveness versus confidentiality: access and sharing of patients' personal health data in order to provide efficient and high-quality care may lead to shared secrecy, which may challenge confidentiality. A further consideration is that of privacy versus common good: privacy may be undermined for the sake of common interests (research, administration, planning and prevention) that benefit the community or population on a great scale.

In the following table, we present the regulation regarding the research integrity and ethical requirements in the context of the SHAPES network involving human participants and the protection of participant data.

Table 5: List of essential principles in SHAPES research and project ethics

ALLEA (2017)	
Reliability	"Reliability in ensuring the quality of research, which is reflected in the design, methodology, analysis and use of resources."
Honesty	"Honesty in developing, undertaking, reviewing, reporting and communicating research in a transparent, fair, full and unbiased way."
Respect	"Respect for colleagues, research participants, society, ecosystems, cultural heritage and the environment."

Accountability	"Accountability for the research from ideation to publication, for its management and organisation, for training, supervision and mentoring, and for its wider impacts."
Beauchamp and Childress (2013)	
Respect for autonomy	The right for an individual to make his or her own choices. Integrity of its members, confidentiality, rights of deceased people
Beneficence	The principle of acting with the best interest of the other.
Non-maleficence	The principle to "above all, do no harm".
Justice	Fairness and equality among individuals.
Belmont Report (1978) on research integrity and applications	
Informed consent	Respecting persons requires that subjects are capable to choose what shall or shall not happen to them. The consent process contains three elements: information, comprehension and voluntariness.
Risk-benefit analysis	It is an opportunity and a responsibility to gather information about proposed research: for the researcher it is a means to examine whether the proposed research is properly designed; for the reviewer it is a method for determining whether the risks presented to subjects are justified; for prospective subjects the assessment will assist them in determining whether or not to participate.
Selection of participants	Fair procedures and outcomes in the selection of research subjects must be applied.
EU Commission (2010), Newman & Brown (1996) and others	
Cultural identity	Respect of cultural identity of the informants.
Sustainability	Responsible use of resources in research.
Diversity	Biodiversity and diversity in management.

2.6 Ethical challenges related to COVID-19

The coronavirus (COVID-19) pandemic of 2019 has affected the entire world, including SHAPES participants' countries. COVID-19 will affect some of the SHAPES schedules. Fundamental rights are being restricted in some countries (like the freedom of movement). Duty of care is the guiding principle when collaborating with older persons and other citizens. Each participant country will follow the national guidelines regarding possible restrictions related to COVID-19, meaning:

- Pilots might have to be rescheduled.
- Project meetings will be organised online until the situation has improved.
- All activities with informants, students, participants etc. during the pandemic will be approached with extra caution.
- Everyone must obey local and global regulations and laws and special arrangements and emergency laws.
- Extra attention will be paid to possible effects of COVID-19 in relation to SHAPES solutions and processes. This will primarily be evaluated afterwards. For example, many older individuals will stay home even more than during "normal times". For instance, in Finland people over 70 are advised not to go out for groceries but instead to avoid stores and interaction. The possible resulting loneliness and mental health issues and perhaps capability to use different devices and applications may increase. The need for SHAPES solutions might be especially interesting in relation to COVID-19 restrictions.

3 Participation of Humans

3.1 General principles

All research will be carried out in a voluntary manner, respecting the autonomy of research participants (Belmont Report 1978; Helsinki Declaration 1964; ALLEA 2017). The rights of all human beings involved in the project will be respected. The freedom of every stakeholder will be guaranteed (Helsinki Declaration 1964; Article 4 of the Additional Protocol; ALLEA 2017).

The research performed within SHAPES will not involve risks and burdens to participants that are not justified in terms of the potential harms and benefits of the research (Article 6 of the Additional Protocol). All research activities carried out within SHAPES will respect the private lives of research participants, and the confidentiality regarding the data collected about them must be guaranteed (Article 25 of the Additional Protocol; ALLEA 2017).

If compensation is offered to SHAPES research participants, it shall not be an incentive to participate in research (Article 12 of the Additional Protocol; ALLEA 2017).

The SHAPES developers and researchers protect, by all necessary means, the safety of participant and minimise all potential risks and burdens that participants may undergo (Article 21 of the Additional Protocol).

The persons participating in SHAPES research will receive full disclosure about the procedure and description of the planned interventions and their implications in comprehensible language before they give or refuse their Informed Consent (Helsinki Declaration 1964; Article 13 of the Additional Protocol; ALLEA 2017).

No research on a person will be conducted without voluntary, freely expressed, specific and documented “Informed Consent” (Helsinki Declaration 1964; Article 14 of the Additional Protocol; ALLEA 2017). Persons participating in SHAPES research may freely withdraw their consent at any stage. This statement is valid for adults and children whom legally have the capacity to consent (Helsinki Declaration 1964).

Persons regarded by law as lacking the capacity to consent will benefit from special protection. Within SHAPES, research cannot be conducted on these persons without permission of legal representatives. Such persons may be, for example, an adult suffering from a mental or cognitive disorder or a mentally disabled person, and permission is required from legal representatives (Helsinki Declaration 1964; Article 15 of the Additional Protocol).

In summary: all researchers and developers must follow local guidelines and laws, including research permits and special arrangements caused by the COVID-19 pandemic.

3.2 *Recruitment of participants*

Voluntary end-users (older people, healthcare providers and other stakeholders) come from both within the partner organisations but also outside them. Participants will be recruited so that the group is representative both from the viewpoint of *social and economic background, age and gender – as well as from the viewpoint of the target groups*. This is important especially when recruiting older persons to WP2 and WP3 work, as well as for end-users of the SHAPES platform during the pilot phase. Detailed recruitment procedures are described as part of WP2 and WP3 work. Detailed recruitment criteria inside each pilot theme will be defined in more detail as part of the WP6 work in D6.1.

Due to the nature of the SHAPES solution, it is essential that vulnerable older people are able to participate in the project, especially under theme 5, “Caring for Older Individuals with Neurodegenerative Diseases”. However, the risk for

stigmatization may not be high, since various types of participants will take part in SHAPES. From the viewpoint of people's Fundamental Rights and Human Capabilities, it is essential that vulnerable people are able to participate. Therefore, appropriate efforts are needed to ensure fully informed understanding of the implications of participation.

Most of the participants in the research and pilots are able to give consent. But since several of them may have diminished cognitive capabilities, special attention will be paid to obtaining and maintaining consents from such individuals. The only pilot theme(s) where participants may be unable to give consent are x and x. However, since SHAPES aims for an ecosystem of services for older individuals, in order to fulfil its objectives and existence on the future, it is essential that those not capable to provide consent be involved in the project. (Lead-users may not be capable representatives for people who are vulnerable). In cases where adults are unable to give informed consent, consent will be acquired from legal representatives. Each organisation conducting research and/or piloting activities with such participants are responsible for acquiring consent and ethics approval and to secure them in a safe place until the end of the project.

3.3 Consent

In the SHAPES project, we must collect consent for several purposes as part of the research activities, dissemination activities and when end-users use the SHAPES platform. Research in which consent will be collected include Ethnography, Focus Groups and Interviews. Dissemination requires consent if personal data will be collected and processed. This is the case, e.g., with newsletter email lists and photography.

The consent document is the basis for communication with the end-users and other stakeholders participating in the project. It consists of the information sheet on the project and the actual consent form. In addition, the information sheet given to potential participants will offer a clear statement of all aspects relevant to their decision about whether or not to participate. Appropriate efforts will be taken to ensure fully informed understanding of the implications of participation. Dissent will be respected.

When it comes to other development activities (e.g., brainstorming sessions and discussions with experts) consent is not needed in general (e.g., when brainstorming with students or having informal discussions). The guidelines of each institution need to be respected; separate permission from the institution may be required if information is gathered about students or staff or about the institution itself (this applies at Laurea UAS, for example). Students are not allowed to pass on information from hospitals or care homes; they are under obligation of

confidentiality (see, e.g., Nursing and Midwifery Council 2019 for handling ethical deviations).

Regarding the research activities as part of WP2, WP3 and WP6, each researcher is responsible for the collection and safekeeping of the templates until the project's conclusion.

In appendixes 3 and 4, you can find a template for the consent and information sheet, which are based on the templates provided by the Ethics Committee for Humanities in Helsinki Metropolitan Area Universities of Applied Sciences. Each organisation conducting research and/or piloting activities are responsible for utilising the templates for obtaining consent (see appendix) and for translating them into the participants' mother tongue. The researcher/pilot organisation will keep the consents on file in a secure setting until the project's conclusion.

In addition, the SHAPES platform itself will obtain consent through a form that follows the above guidelines. The service design can be applied in designing the consent in such a way that it is usable for the SHAPES users. Detailed requirements regarding the consent on the SHAPES platform will be defined in D8.4 and D8.14. Consent collected by the SHAPES platform will be kept on file on the SHAPES platform.

3.4 Co-creation with citizens

Inalienable principle is that all human beings have a dignity, an intrinsic worth, that is not subject to trade-off. Dignity of all persons must be respected at all times (see also European Commission 2013).

SHAPES and its methodology are strongly based on collaboration and co-creation with end-users and other stakeholders. This means that one need not only to collect consent and secure personal data but also consider how collaboration is performed. Our knowledge interests, especially when working with end-users and other stakeholders, are strongly hermeneutical and emancipatory.

We support end-users to be empowered, active agents of change in their lives and in society. Instead of being merely inputs in the SHAPES project, end-users are themselves subjects of outcomes and impacts. In order to enable this, a capabilities approach is applied in the design of the co-creation activities with the older persons (see table below). The capabilities of *Senses, Imagination and Thought, Practical Reason, Affiliation and Control over own Environment* are all to be supported (see Sarlio-Siintola 2011).

Table 6: The Central Human Capabilities by Nussbaum

1. *Life*. Being able to live to the end of a human life of normal length; not dying prematurely or before one's life is so reduced as to be not worth living.
2. *Bodily Health*. Being able to have good health, including reproductive health; to be adequately nourished; to have adequate shelter.
3. *Bodily Integrity*. Being able to move freely from place to place; to be secure against violent assault, including sexual assault and domestic violence; having opportunities for sexual satisfaction and for choice in matters of reproduction.
4. *Senses, Imagination and Thought*. Being able to use the senses, to imagine, think, and reason—and to do these things in a “truly human” way, a way informed and cultivated by an adequate education, including, but by no means limited to, literacy and basic mathematical and scientific training. Being able to use imagination and thought in connection with experiencing and producing works and events of one's own choice, religious, literary, musical, and so forth. Being able to use one's mind in ways protected by guarantees of freedom of expression with respect to both political and artistic speech and freedom of religious exercise. Being able to have pleasurable experiences and to avoid non-beneficial pain.
5. *Emotions*. Being able to have attachments to things and people outside ourselves; to love those who love and care for us, to grieve at their absence; in general, to love, to grieve, to experience longing, gratitude, and justified anger. Not having one's emotional development blighted by fear and anxiety. (Supporting this capability means supporting forms of human association that can be shown to be crucial in their development.)
6. *Practical Reason*. Being able to form a conception of the good and to engage in critical reflection about the planning of one's life. (This entails protection for the liberty of conscience and religious observance.)
7. *Affiliation*.
 1. Being able to live with and toward others, to recognize and show concern for other humans, to engage in various forms of social interaction; to be able to imagine the situation of another. (Protecting this capability means protecting institutions that constitute and nourish such forms of affiliation and also protecting the freedom of assembly and political speech.)
 2. Having the social bases of self-respect and non-humiliation; being able to be treated as a dignified being whose worth is equal to that of others. This entails provisions of non-discrimination on the basis of race, sex, sexual orientation, ethnicity, caste, religion, national origin and species.
8. *Other Species*. Being able to live with concern for and in relation to animals, plants and the world of nature.
9. *Play*. Being able to laugh, to play, to enjoy recreational activities.
10. *Control over one's Environment*.
 1. *Political*. Being able to participate effectively in political choices that govern one's life; having the right of political participation, protections of free speech and association.
 2. *Material*. Being able to hold property (both land and movable goods) and having property rights on an equal basis with others; having the right to seek employment on an equal basis with others; having the freedom from

unwarranted search and seizure. In work, being able to work as a human, exercising practical reason and entering into meaningful relationships of mutual recognition with other workers.

The methods and tools to be used in the co-creation with the older persons will be chosen carefully by taking into account their capabilities to function, so that there will be no burden for, e.g., vulnerable participants or any risk for stigmatization. All direct costs for participants will be covered by the project. None of the older individuals involved in the project are hospitalized patients, but some live in nursing homes or attend day care centres, and others are monitored by health and wellbeing platforms at home to reduce their visits to doctors, connect with their doctors from home and contribute to rehabilitation programmes or medicine adherence regimes.

3.5 Research integrity and ethical requirements for pilots with real users

The ethical issues that have emerged from user involvement in SHAPES is a crucial matter that must be considered by the consortium. It is of utmost important to pay special attention to ethical scientific research, because it is an area both directly and indirectly involved with human subjects. Within the European Commission ethics framework, we need to consider a series of issues and ensure that the SHAPES project adheres to the below:

1. Respects the integrity and dignity of persons (that this intrinsic worth protects them from being used for greater perceived benefits)
2. Follows the “do no harm” principle; any risk must be clearly communicated to subjects
3. Recognizes the rights of individuals to privacy, personal data protection and freedom of movement
4. Honours the requirement of informed consent and continuous dialogue with research subjects
5. Respects the principle of proportionality: not imposing more than is necessary on subjects or going beyond stated objectives
6. Treats societal concerns seriously – a researcher’s primary obligation is to listen to the public and engage with them in constructive dialogue: transparently, honestly and with integrity
7. Recognises the wholeness of an individual and that any modification (genetic or technological) does not interfere with this principle
8. Respects biodiversity and does not impose irreversible change that threatens the environment or ecological balance

9. Builds on the understanding that any benefits are for the good of society and any widely shared expressions of concern about threats from your research must be considered (with the acceptance that certain research practices may have to be abandoned)
(European Commission, 2007)

3.6 Processing of personal data during the SHAPES project

3.6.1 Processing of personal data during research activities

The collection and processing of personal data in the SHAPES project during the ethnography, focus groups, workshops, surveys and interviews will be minimised. But since personal data is needed, the GDPR is applied. Data minimisation and anonymisation/pseudonymisation will be applied in the processing of research data (see the Data Management Plan, D8.13).

On the consent form, participants will be clearly informed about the purpose behind the processing of their data and how it will be used (see appendixes 4 and 5). This will be included in the informed consent form. Detailed procedures for data collection, storage, protection and retention, as well as detailed safety procedures, are to be described in the Data Management Plan (D8.13) and in SHAPES data processing records.

Specific health-related partners will also bring their databases containing health-related information (previously collected information) for development work. However, this data is anonymised and used only for the testing and validating the SHAPES solution before deployment to real-life scenarios.

Each organisation processing personal data as part of its research activities must nominate a Data Protection Officer and Data Owners.

3.6.2 Processing of personal data on the SHAPES platform during pilots

Requirements for processing of health data and other personal data on the SHAPES platform as part of its service production is described in D8.4 and D8.13. The implementation of these features is in turn described in various technical deliverables.

The development versions of the SHAPES platform to be piloted must fulfil the requirements of the GDPR, defined in D8.4 (ethical requirements). Each pilot will therefore conduct a Data Protection and Privacy Impact Assessment (DPIA) prior to each pilot. Each pilot must nominate the Data Protection Officer and define the Data Protection Policy for each pilot (see the template in the annex).

The consent for processing end-users' personal data on the SHAPES platform during the pilots can be collected and stored either on the SHAPES platform or manually.

4 Incidental findings

4.1 *Incidental Findings in the Healthcare context*

In the context of health research, the term “incidental findings” (IF) is used to indicate unexpected positive findings. The terms “serendipitous and iatrogenic”, “non-incidental secondary findings”, “unanticipated findings” and “off-target findings” describe these findings particularly when they are actively sought, not unexpectedly discovered (Green et al. 2013).

In public health programs, the incidental findings may be social benefits resulting in, e.g., greater employment or the strengthening of communities (Kass 2001). An ethical dilemma due to the incidental findings requires a tailor-made, evidence-based plan anticipating the potentially beneficial or harmful consequences and their relative importance for the participants in assistance of a case-specific risk-benefit analysis. Ethical challenges related to respect of patient autonomy, privacy and interests entails consideration of the patient’s preferences about disclosure of incidental findings. This make it necessary for the testers and researchers to define a protocol for incidental findings prior to testing. Such protocol includes: 1) description of potential findings that may arise, 2) a plan for dealing with any findings and 3) disclosure of the plan to the participants. In a case where the evidence related to benefits and harms is not clear, planning requires provisions for describing potential benefits and risks to participants and assisting them in decision-making on the basis of their own values and preferences (Ells and Thombs 2014); for a template, see the attachment. (Weiner 2014). In the SHAPES project, the (non)disclosure plan for incidental findings is included in both the development/research plan and in the consent form for participants.

4.2 *Incidental findings and other sensitive information in the context of SHAPES*

“Incidental findings” refers to any unexpected finding that:

- results from the data collection activities conducted in the Action, especially the data collection with older individuals and caregivers, namely during pilot activities, interviews and observations;
- is not related to the object of the research;
- concerns instances that, based on the researcher’s knowledge and judgment, are evidently illegal or potentially critical for safety and security.

This means that in SHAPES, an incidental finding related to a health condition may emerge both during the research with the end-users and as a consequence of data processing on the SHAPES platform (see the first row of the table below).

The first bullet point is related to research integrity and is quite similar to the situations described above in the subsection “Incidental Findings in Health Research”. The last point is related to the use of big data and AI during the service provision of various SHAPES services during the pilots and after the project when the system is in use.

However, if we in SHAPES widen the perspective of incidental findings outside the health condition of an individual, we may discuss that sensitive information that emerged during the following situations:

- ethnographic research with the older people
- research related to the conops and SHAPES ecosystem
- service provision on the SHAPES platform for the older people
- information service provision on the SHAPES platform for researchers, healthcare organizations etc.

Sensitive information may be related to, e.g., the following cases, either intentionally or unintentionally:

- information about the misuse of a service/system by an individual client or by several clients
- information about the systematic misuse of a service/system by several clients
- information about the unethical activities/decision-making on the level of an organisation and a single worker
- information about systematic unethical activities/decision-making on the level of an organization (or even the whole ecosystem)

Table 6: Incidental findings (IF) and sensitive information (SI)

	SHAPES (e.g., WP2 ethnographic) research activities with the older people	SHAPES research activities with service providers and other stakeholders	The use of the SHAPES ecosystem on a micro level	The use of the SHAPES ecosystem and big data on a macro level
Incidental findings (IF) on an individual's health condition (e.g., a new undiagnosed disease)	IF may emerge during ethnographic research		IF may emerge from the analysis of an individual's health and other data	
Sensitive information (SI) on the organisational level related to an individual (e.g., misuse/unethical activity of the client)	SI may emerge during ethnographic research	SI may emerge during interviews etc. related to the CONOPS	SI may emerge from the analysis of individuals' health and other data	

SI on the organisational level related to misuse/unethical activities of several clients		SI may emerge during interviews etc. related to the CONOPS		Big data analytics may reveal systematic misuse
SI on the level of organisation and unethical activities/decisions of a single worker	SI may emerge during ethnographic research	SI may emerge during the interviews etc. related to the CONOPS	SI may emerge from the analysis of individuals' health and other data	
SI on the level of organisation and systematic unethical activities/decisions by several actors	SI may emerge during the ethnographic research	SI may emerge during the interviews etc. related to the CONOPS		Big data analytics may reveal systematic misuse

4.3 Activities/procedures related to incidental findings and sensitive information during the SHAPES project and on the SHAPES platform

4.3.1 Incidental findings and sensitive information during research

In the SHAPES project, the (non)disclosure plan for incidental findings is included both in the development/research plans and in the consent form for participants (see the consent form in the appendix).

Research plans that may involve a risk of incidental findings must be accepted either by the organisation's own board of ethics (e.g., at universities), or if the organisation does not have such, then at the SHAPES EAB. The plan for incidental findings must be sent to the WP8 internal review team for comments.

If incidental findings are identified in the context of SHAPES activities, they must be reported to the relevant authority or to the responsible organisational role, as well as the EM.

The ethics of ethnography is essential within SHAPES project ethics: informed consent and the application of it to different populations, relationship issues, risk, covert issues and reciprocity are essential in the ethics of ethnography. This applies to SHAPES. Ethnography is based on the interaction between the subject and the researcher; therefore, the relationship between the subject and the researcher is multifocal and close, and the roles may be vague—it might be unclear whether a person is in the role of researcher, clinician or friend (Lipson 1994). Special attention needs to be paid to subjects in vulnerable positions.

4.3.2 Incidental findings on the SHAPES platform during service provision

The issue of incidental findings on the SHAPES platform during the service provision stage for older individuals is related to the ethics and quality of the SHAPES ecosystem. The ethical requirements for the procedures are therefore described in “Ethical framework for SHAPES” D8.4 (M6) and D8.14 (M18).

The issue of incidental findings is also related to the quality of the various SHAPES services and data analytics. A key task is to eliminate false positive and false negative results. These are discussed in documents D8.4 and D8.14.

4.3.3 Sensitive Information revealed through the SHAPES platform and its data analytics

The issue of sensitive information on the SHAPES platform when providing population level information services are related to the ethics and quality of the SHAPES ecosystem. The ethical requirements for these procedures will be described in the “Ethical framework for SHAPES” D8.4 and D8.13 (M18) documents.

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6 Attachments

1 Ethical self-assessment template

2 Ethics compliance check template

3 Consent template for research in which health data and other personal data is collected

4 Information sheet template

5 Data protection policy template for SHAPES research activities

ETHICAL SELF-ASSESSMENT FOR THE RESEARCH OF EACH WORK PACKAGE (ANNEX 1)

This evaluation form is based on the ethics self-assessment template of Horizon 2020 projects. (https://ec.europa.eu/research/participants/data/ref/h2020/grants_manual/hi/ethics/h2020_hi_ethics-self-assess_en.pdf).

Ethics self-assessment should be completed for all SHAPES research/development/piloting tasks. Work package leaders should make sure that it will be done. WP leaders are kindly asked to fill in the template and upload to Teams.

Work package/pilot	
Form completed by (name & partner)	
Date	

1. HUMAN EMBRYOS/FOETUSES	
Does your research involve Human Embryonic Stem Cells (HESCs)?	<input type="checkbox"/> yes <input type="checkbox"/> no
If yes, please specify. Wait for further instructions from the ethics committee before starting the R&D work.	
2. HUMANS	
Does your research involve Human Participants?	<input type="checkbox"/> yes <input type="checkbox"/> no
<p>Activities to be taken (if yes):</p> <p>1) Always respect human dignity and the intrinsic value of the individuals.</p> <p>2) The researchers and pilot organizations should provide participants' consent forms with an information sheet specifying the nature of the research. The template for the consent and information sheets are available in Teams WP8 and in D8.2. The documents have to be written in the participant's language. The researcher/pilot organisation will keep the consent forms on file in a safe place until the end of the project. Edited & translated documents are to be uploaded also to WP8 Teams.</p> <p>3) A written research plan must be provided, including details of the recruitment, types of vulnerability and diseases, inclusion and exclusion criteria and informed consent procedures. If people unable to provide consent will be involved, the procedures for obtaining approval from the legal representative must be described in detail. In addition, the plan must demonstrate appropriate efforts to ensure fully informed understanding of the implications of participation.</p> <p>4) Ethics approvals by local authorities must be acquired and kept on file (e.g., when involving vulnerable persons and persons unable to give consent. This also applies in the situation with Covid-19 pandemic.</p>	



5) The methods and tools to be used in co-creation with the older persons will be chosen carefully by considering their capability to function, so that there will be no burden for, e.g., vulnerable participants, or any risk for stigmatisation. All direct costs for participants will be covered by the project.	
3. HUMAN CELLS / TISSUES	
Does your research involve human cells or tissues (other than from Human Embryos/ Foetuses, i.e., section 1)?	<input type="checkbox"/> yes <input type="checkbox"/> no
If yes, please specify. Wait for further instructions from the ethics committee before starting the R&D work.	
4. PERSONAL DATA	
Does your research involve personal data collection and/or processing?	<input type="checkbox"/> yes <input type="checkbox"/> no
Does it involve tracking or observation of participants?	<input type="checkbox"/> yes <input type="checkbox"/> no
Does your research involve further processing of previously collected personal data (secondary use)?	<input type="checkbox"/> yes <input type="checkbox"/> no
<p>Activities to be taken (if yes):</p> <p>1) Informed consent forms collected from the participants are the general prerequisite for this data processing (on the consent procedures, see also part 2, Humans).</p> <p>2) Researchers should provide details regarding the procedures of the collection, storage, protection, retention, transfer and destruction or re-use of data, as well as those regarding data safety procedures, data transfers to third countries and tracking and observing methods. This activity is part of the data management plan.</p> <p>3) The SHAPES data processing description is filled out and uploaded to Teams. (see Data Management Plan D8.13)</p> <p>4) The Data Protection Officer and Data Owner have been nominated.</p> <p>5) The DPIA has been completed and required actions implemented (pilots only.)</p>	
5. ANIMALS	
Does your research involve animals?	<input type="checkbox"/> yes <input type="checkbox"/> no
<p>Activities to be taken:</p> <p>The researchers should obtain the necessary authorisations and provide a detailed analysis of the procedures, justifications and legal compliance.</p>	



6. THIRD COUNTRIES	
Does your research involve non-EU countries?	<input type="checkbox"/> yes <input type="checkbox"/> no
Do you plan to import any material from non-EU countries into the EU?	<input type="checkbox"/> yes <input type="checkbox"/> no
Do you plan to export any material from the EU to non-EU countries?	<input type="checkbox"/> yes <input type="checkbox"/> no
<p>Activities to be taken:</p> <p>The researchers should provide a risk-benefit analysis, the details of the activities and compliance checks with the EU and local legislations.</p>	
7. ENVIRONMENT and HEALTH and SAFETY	
7a) Does your research involve the use of elements that may cause harm to the environment, animals or plants?	<input type="checkbox"/> yes <input type="checkbox"/> no
7b) Does your research involve the use of elements that may cause harm to humans, including research staff?	<input type="checkbox"/> yes <input type="checkbox"/> no
<p>Activities to be taken 8 (if yes):</p> <p>7a: The researchers should obtain the necessary environmental authorizations and provide a risk-benefit analysis and compliance checks regarding legislation.</p> <p>7b: The researchers should obtain the necessary health and safety authorizations and provide the details of safety procedures and legal compliance.</p>	
8. DUAL USE	
Does your research have potential for military applications?	<input type="checkbox"/> yes <input type="checkbox"/> no
<p>Activities to be taken (if yes):</p> <p>If yes, contact EM and ET immediately.</p>	
9. MISUSE	
Does your research have the potential for malevolent/criminal/terrorist abuse?	<input type="checkbox"/> yes <input type="checkbox"/> no
<p>Activities to be taken (if yes):</p> <p>The researchers should provide a risk assessment and impact on human rights, the details on the applicable legal requirements and the measures to be taken to prevent abuse.</p>	
10. INCIDENTAL AND/OR SENSITIVE FINDINGS	



Does your research involve a risk of incidental findings?	<input data-bbox="967 230 1015 282" type="checkbox"/> yes <input data-bbox="1094 230 1142 282" type="checkbox"/> no
11.Data Management	
Is your WP responsible for providing Data Management Plan? (see D8.13) If yes, provide the plan and update is in Teams.	



ANNEX 2: ETHICS COMPLIANCE CHECK OF EACH SHAPES DELIVERABLE

The focus of this compliance is on the ethical, legal and societal requirements defined in D8.4 and which pose impact on the SHAPES solution. The left column contains ethical issues relevant from the viewpoint of the SHAPES solution, including technology, user processes of various user groups, business and governance models, as well as the whole ecosystem (more detailed ethical requirements based on these topics can be found in D8.4).

Ethical issue	Key work packages	How we have taken this into account
Protect and promote EU Fundamental Rights of older individuals and other end-users	WP8,WP3,WP2 (>WP4, WP5,WP6) WP7, WP9	
Consider The Ethics of Care and Biomedical Ethics	WP8, WP2,WP3 (>WP4, WP5, WP6)	
Protect and promote Human Capabilities of older individuals and other end-users	WP8, WP2,WP3 (>WP4, WP5, WP6) WP7, WP9	
Consider UN Sustainable Development Goals	WP8, WP3, WP7, WP9	
Consider Corporate Social Responsibility (CSR)	WP8, WP3, WP7, WP9	
Consider EU ethical guidelines and white paper for Artificial intelligence	WP8, WP3, WP9 WP4, WP5	
Be compliant with the Legal framework for pan-European Smart and Healthy Ageing	WP8, WP3, WP7, WP9	
Be compliant with the Legal framework for privacy and data protection	WP8, WP2, WP3, WP7, WP8, WP9 WP4, WP5	



Apply Network and Information Security Directive (NIS)	WP8, WP3, WP4, WP5	
Design and implement Supported decision-making in the context of the SHAPES ecosystem	WP8, WP2, WP3	
Promote Digital inclusion and the sense of security of the ageing individuals	WP8, WP2, WP3 (>WP4, WP5)	
Consider The moral division of labour in digital service providing with and for the older persons	WP8, WP3, WP7, WP9	
Consider Welfare technology and attraction of the older persons care work	WP8, WP3, WP2	
Consider Movement of caregivers across Europe	WP8, WP3, WP9	
Apply Customer logic approach and Service Design	WP3, WP7, WP9	
Apply Cyber Security requirement	WP4, WP5	
Be aware and consider ethical challenges of single SHAPES services and their use as part of the Ecosystem	WP8, WP3, WP6	



ANNEX 3: SHAPES PARTICIPANT CONSENT FORM

Title of the study: [insert title of the study]

Location of the study: [Insert name and the contact details of the organisation and the researcher conducting the study. Insert also the contact details of the responsible researcher and SHAPES-project coordinator]

I have been invited to participate in the above research study. The purpose of the research is [provide a brief and simple description for the participant to understand explanation of what are you intending to achieve by the research]

I have read and understand the participant information sheet. The information sheet has provided me sufficient information about the above study, its purpose and execution of the study, about my rights, as well as about the benefits and risks involved. I have had the opportunity to ask questions about the study and have had these answered satisfactorily.

I have been given sufficient information about the collection, processing, transfer/disclosure and deletion of my personal data during the study, and the Privacy Notice and [insert here potential national guidelines for research integrity] have been available as part of the SHAPES project Participant Information documents.

By signing this form, I confirm that I voluntarily consent to participate in this study and that I **also** grant consent to the processing of my personal data for the purposes described in this document and in the privacy notice.

I have not been pressurized or persuaded into participation and I have had enough time to consider my participation in the study. I understand that my participation is entirely voluntary and that I am free to withdraw my consent at any time, without providing any reason.

I also have the right to request the removal of my identifiable personal data in accordance with data protection regulation. I am also aware that if I withdraw from the study or withdraw my consent, any data other than personal information collected before my withdrawal can be included in the research/development/innovation data.

Date and place

Signature of Participant

The original consent signed by the participant and a copy of the participant information sheet will be kept in the records of the researcher/developer/innovator. The participant information sheet,



privacy notice and a copy of the signed consent will be given to the participant.

SHAPES-project PARTICIPANT INFORMATION SHEET

ANNEX 4

This template includes essential information you are obliged to provide to research participants. This template is a guide to help researchers/developers/innovators design study information sheets. You can alter the text as necessary for your study, but headings should remain (if not mentioned otherwise). Please note that an information sheet regarding the use of the SHAPES platform will be provided later on.

Study title: [One consistent title should appear on all your study documents]

Invitation to participate in a [research/development /innovation] study
[For example: We'd like to invite you to take part in our research study, during which.... provide a brief outline of the purpose of your study in lay language. You should explain briefly why and how the participant was invited/chosen/recruited. State how many participants you are intending to involve.]

This information sheet describes the study and your role in it. Before you decide, it is important that you understand why the [research/development /innovation] is being done and what it will involve for you. Please take time to read this information and discuss it with others if you wish. If anything is not clear, or if you would like more information, please ask the person responsible for this study. After that we will ask you to sign a consent form in order to participate in the study.

Voluntary nature of participation

Participation in this study is voluntary. You can withdraw from the study at any time without giving any reason and without there being any negative consequences. If you withdraw from the study or withdraw your consent, any data other than personal information collected from you prior to withdrawal can be included in the research data.

Purpose and aims of the study

Provide a paragraph to describe the [research/development /innovation] study and why it is being done. Include the purpose and main aims of the study in brief.

Who is organising and funding the research?

Describe the consortium that is organising and funding the research. Name the lead organisation and the responsible organisation and researcher/developer/innovator. What's the role of your organisation in this research? Who is financing the research?

What will the participation involve?

You should give potential participants an idea of what they should expect if they agree to take part. What sort of information will be sought and why the collection of this information is relevant for achieving the objectives of the study. It is important that you consider participant's perspective.

What exactly will happen – e.g., collecting personal information, questionnaires, interviews, focus



groups, tests, physical measurements, [for medical and physiological data, an ethical review from a local university district or medical ethical review board in Finland may be needed=> please, check your local legislation and practices] use of any recording (audio, video), location data or photographs etc.

What is the research method used?

Where is the research taking place?

Possible benefits of taking part

Any benefits to the participants that can reasonably be expected should be stated. If there are none, this should also be stated. Indirect benefits, such as potential benefits to future patients, the wider community and/or contributing to knowledge can be included here.

Possible disadvantages and risks of taking part

Any reasonably foreseeable discomforts, disadvantages and risks for the participants need to be stated.

Incidental findings

Participation in this study...

Financial information

Participation in this study will involve no cost to you. You will receive no payment for your participation. You should explain if reimbursements (e.g., travel, meals) are available. Inform potential participants which organisations are funding / sponsoring your research.

Insurance policies

Insurance policies possibly taken out for the participants should be indicated here. Delete this item if not relevant.

Informing about the development / innovation / research results

Describe how the results or a summary of the results will be made available to the participants. Reassure potential participants that they will not be identified from any report or publication placed in the public domain].

Termination of the study

The developer / Innovator / researcher(s) conducting the study can also terminate the study... mention any foreseeable reasons for termination.

Further information

Further information related to the study can be requested from the researcher / person in charge of the study.

Contact details of the researchers / person in charge

Name at least the principal investigator and the person in charge of the study. [insert name and the contact details of the researcher conducting the study.

Researcher / person in charge / student name:

Telephone number:

Email:



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ANNEX 5: Privacy Notice/Policy for SHAPES research data

If you don't process personal data during this research study, you can leave this appendix out. Please note that the information sheet regarding the use of the SHAPES platform will be provided later on.

Within the SHAPES project, your personal data will be processed according to the European Union General Data Protection Regulation (679/2016) and current national regulation. The processing of personal data will be described in the following items.

Data controller of the SHAPES project

[Data controller is the natural or legal person, public authority, agency or other body who alone or jointly with others determines the purposes and means of the processing of personal data].

Write the name of the data controller: organisation name and address.

If there are two or more controllers who jointly determine the purposes and means of processing personal data as part of this research, they are joint controllers. Describe the roles and the division of responsibilities between the parties here.

Contact person for matters related to the processing of personal data

Provide the name, email address and phone number of the contact person for matters related to the processing of personal data.

Types of personal data that will be collected in this study

Provide all of the personal data and personal data types you will process. If necessary, you can use a separate appendix. Personal data can be, e.g., a name, a personal identity code, an email address that contains a real name, facial data, voice data, fingerprints, the iris of an eye, the shape of a palm, a traditional signature, an address, a phone number, an IP address, a student identification number, an insurance number, an account number, detailed income information, a given title such as a chairmanship, gender, age, home municipality, profession, place of study, specific dates (date born, date died, time of an event) as well as sensitive data (race, ethnic origin, political opinions, religious or philosophical beliefs, trade union membership, genetic or biometric data, health data, sexual orientation etc.).

Describe whether personal data will be collected from other sources; for example, from official registries. What kind of data will be collected and on what basis?

Personal data protection principles

Describe the information systems, software, applications etc. used for collecting and processing personal data.

Describe how the information systems has been protected. *For example:*

The data that is to be processed in the information systems has been protected using the following:
user ID ☐ password ☐ user registration ☐ access control (physical location) ☐

If other methods, please specify:

For what purpose will personal data be processed?

Please write a short description of the purpose of the study.



Legal basis of processing personal data

Please enter the same legal basis as you have provided in the privacy notice.

In scientific research, the legal basis is usually a task carried out in the public interest.

You have the right to withdraw the consent at any time as described in this notice.

Nature and duration of the study completed within the SHAPES project (how long the personal data will be processed):

One-time research ☐ Follow-up research

Duration of the research:

This is the time frame needed for collecting and analysing the data and for the publication of the study (plus three years for possible reclamations about the research results and time needed to respond).

What happens to the personal data after the study within the SHAPES project has ended?

Please describe the measures to be taken at the end of the study regarding whether the personal data be destroyed or archived and for how long. *For example:*

How the personal data will be processed after the study has ended:

If any research materials containing personal data will be destroyed

If any research materials containing personal data will be archived

without identifiers

with identifiers

Where the materials will be archived and for how long:

Data transfer outside of the research registry:

Please describe whether personal data will be transferred outside the research group (to whom and for what purpose). Please also take into account possible transfers to data processors (for example translators).

Possible transfer of personal data outside the EU or the EEA:

Please describe if data will be transferred to a third country. *For example:* Your data will not be / will be transferred outside of the EU or the EEA.

If yes, specify the data to be transferred, the purpose and the object of the transfer, as well as the legal basis for the transfer in line with the GDPR.

Your rights as a data subject

Because your personal data will be used in the study taking place within the SHAPES project, you will be entered into the study registry. Your rights as a data subject are the following:

Of the following two options, please choose the one that is in line with your processing basis and delete the extra text. It is sufficient to enter a list of the rights and to mention how they can be exercised. [N.B. Add open data]

If your *processing basis is a task carried out in the public interest*, please list the following rights:

Right to obtain information on the processing of personal data

Right of access



Right to rectification
Right to restriction of processing
Notification obligation regarding rectification of personal data or restriction of processing
Right to object to the processing
Right not to be subject to a decision based solely on automated processing
Right to notify the Data Protection Ombudsman if you suspect that an organisation or individual is processing personal data in violation of data protection regulations.

You can exercise your rights by contacting the data controller of the study.

If your processing basis is consent granted by the data subject, please list the following rights:

Right to obtain information on the processing of personal data
Right of access
Right to rectification
Right to erasure (right to be forgotten)
Right to withdraw consent regarding processing of personal data
Right to restriction of processing
Notification obligation regarding rectification or erasure of personal data or restriction of processing
Right to data portability
The data subject can allow automated decision-making with his or her specific consent
Right to notify the Data Protection Ombudsman if you suspect that an organisation or individual is processing personal data in violation of data protection regulations.

If the purposes for which a controller processes personal data do not or no longer require the identification of a data subject by the controller, the controller shall not be obliged to maintain, acquire or process additional information in order to identify the data subject for the sole purpose of complying with this regulation. If the controller cannot identify the data subject, the rights of access, rectification, erasure, notification obligation and data portability shall not apply, except if the data subject provides additional information, enabling his or her identification.

You can exercise your rights by contacting the data controller of the study.

Personal data collected in the SHAPES project for research will not be used for automated decision-making. In the SHAPES project studies, the processing of personal data is never used in any decisions concerning the participants of the research.

Pseudonymisation and anonymisation

Please modify the next two chapters to suit your study and delete the unnecessary parts:

All information collected from you will be handled confidentially and according to the legislation. Individual participants will be given a code, and the data will be stored in a coded form in the SHAPES project files. Results will be analysed and presented in a coded, aggregate form. Individuals cannot be identified without a code key. A code key, which can be used to identify individual research participants and their responses, will be stored (by whom), and the data will not be given to people outside the SHAPES-project study group. The final research results will be reported in aggregate form, and it will be impossible to identify individual participants. The SHAPES project study registry will be stored (where) for (XX) years, after which it will be destroyed (please describe how). (Or alternative method).



The SHAPES professionals must inform participants if the collected data will be used for later research (for example “The data collected from you can be later...”). The participant has the right to request information of people who have received data for their use...). If the legal basis for processing personal data has been consented, and you wish to use the data in further studies, a specific consent for that must be obtained. Please mention if you intend to cooperate internationally and clarify the confidentiality and protection of the data as well as possible agreements on data processing.

