



# SHAPES

Smart and Healthy Ageing  
through People Engaging in supporting Systems

## D8.1 – Set-up Ethical Advisory Board

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0.5	31/01/2020	Sari Sarlio-Siintola (LAUREA)	Chapters 1-6
1.0	13/04/2020	Sari Sarlio-Siintola (LAUREA)	Version including EAB members (3.3) and updated descriptions of the EAB work
1.1	26/04/2020	Karoliina Nikula, Sari Sarlio-Siintola	Comments from reviewers included in the deliverable
1.2	30/04/2020	Sari Sarlio-Siintola	Refinements based on the issues discussed at the wp8 meeting

## Table of Contributors

Table 2 Deliverable Contributors

Section	Author(s)
Table of Contents	Sari Sarlio-Siintola (LAUREA)
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## Table of Acronyms and Abbreviations

Table 3 Acronyms and Abbreviations

Acronym	Full Term
DPM	Data Protection Manager
EAB	Ethics Advisory Board
EM	Ethics Manager
ET	Ethics Team
GA	Grant Agreement
WPL	Work Package Leader

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## Keywords

ETHICS ADVISORY BOARD, ETHICS GOVERNANCE

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## Executive Summary

This deliverable lays out the composition of the Ethical Advisory Board (EAB) and its working practises. The EAB has been established for the purpose of supporting the SHAPES Project. It is a consultative body which will help to ensure and strengthen the high ethical standard of the SHAPES project and to support the consortium on ethical issues arising. This document may be updated as a working document should the composition of the EAB change.



# 1 Introduction

## 1.1 Rationale and purpose of the deliverable

*“The Ethical Advisory Board (EAB): The EAB is responsible for providing consultation and suggested rulings in any circumstance that project activities might potentially involve Ethics, Privacy and relevant Regulation implications. The EAB’s actions can be requested by the Coordinator or WPL or self-invoked as result of WP8’s research ethical monitoring. The Board will oversee any relevant informed consent procedures as well as ethical and data protection authorisations required for the project. The Board will help define the project baseline for research ethics and ethics by design against which all project activities and deliverables will be checked to ensure compliance with all relevant standards for responsible research. The EAB is chaired by LAUREA. The EAB will be composed of experts in the sector coming from consortium partners, relevant stakeholders and at least two external members” (SHAPES 2019).*

This deliverable lays out the composition of the Ethical Advisory Board (EAB) and its working practises. This deliverable builds on the SHAPES Grant Agreement (SHAPES 2019), and follows also well-established guidelines on EAB and its working practises. These guidelines include “How to complete your Ethical Self-Assessment” (EU2019) and “Roles and Functions of Ethics Advisors/Ethics Advisory Boards in EC-funded Projects” (EU 2012).

The EAB is a group of ethics experts giving advice to consortium partners in the context of the work of the SHAPES project. The work of these experts should facilitate, build upon and complement existing oversight regimes by competent ethical and legal authorities in partner institutions and countries. The consideration of ethical issues enhances the quality of research and innovation actions in SHAPES, protects participants and researchers, increases its social impact, promotes research integrity, promotes a better alignment of research with social needs and expectations and, finally, supports the societal uptake of the fruits of research - because high ethical standards generally merit public trust (see EU 2012).

The EAB will advise on its own initiative, as well as upon request. The EAB will work closely with the Work Package 8 “SHAPES Legal, Ethics, Privacy and Fundamental Rights Protection” and Work Package 1 “Project Management”.

Ethics is to be seen as an essential component of the SHAPES innovation action process. In that vein, ethics is not a burden. Rather, it can be perceived as an approach to create more value to society and better innovation actions in SHAPES project. For



this reason, the relationship between the EAB and the research team will be collaborative and constructive.

## *1.2 Structure of the document*

After this introduction, in Chapter 2 we discuss the SHAPES project from an ethics point of view. In Chapter 3 we report the members of the EAB and the criteria used to recruit those members. In Chapter 4 we outline the basic principles and guidelines for EAB's work. Chapter 5 provides some concluding remarks.





## 2 SHAPES and Ethics Work

### 2.1 Ethical Aspects in SHAPES project

Ethics in the SHAPES project includes both issues related to the SHAPES research and development work (the process and research integrity), as well as the definition and implementation of features of the SHAPES solution in accordance with the ethical requirements (ethical features of the solution to be created).

SHAPES pilots are multifaceted from an ethics viewpoint as they concern ethics directly related to the safety of participants and researchers, research and development activities, validation of the ethical features the SHAPES platform, and the use of SHAPES in real-time settings. Pilot environments will be validated to ensure the settings fulfil the minimum legal requirements.

By investigating ethical issues related to the process and to the solution, we will endeavour to incorporate ethical aspects in all phases of the project making them understandable by all stakeholders (e.g. research participants, researchers, technology developers, business and ecosystem modellers, civil society and other actors).

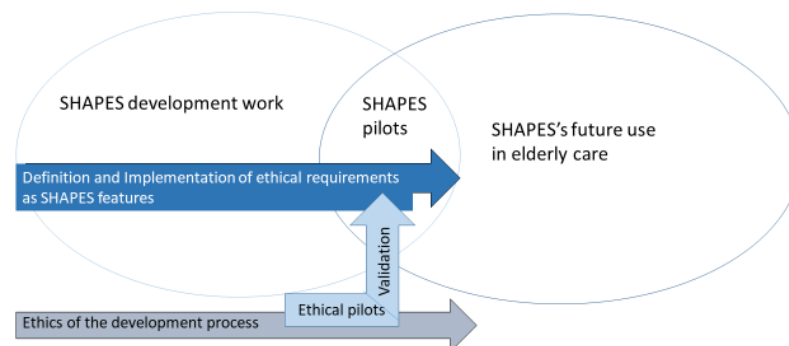


Figure 1: Ethical dimensions in the SHAPES project

### 2.2 Ethics Governance

In order to properly address the ethical, social and legal issues, the SHAPES consortium has introduced a dedicated work package within the project. While SHAPES researchers and developers will take into account ethical and social aspects in each of the projects' work packages (WPs) and tasks, special attention is dedicated

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to these issues in 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 Figure 2 on SHAPES Ethics Governance Model).

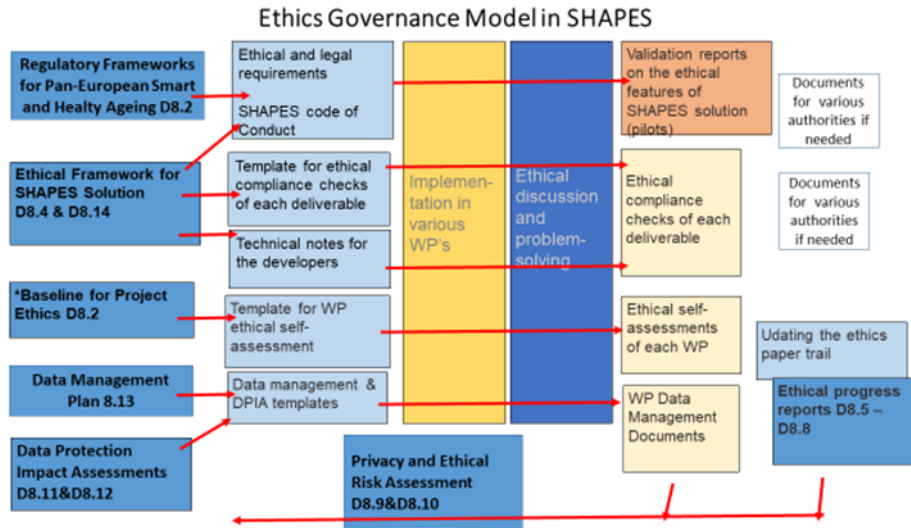


Figure 2: SHAPES Ethics Governance Model

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. Ethics Manager (LAUREA) will monitor and report of the status of the project with respect to ethical compliance and the ethical implications of innovation. The Data Protection Manager (LAUREA) will be responsible for decisions about the protection and management of data gathered during the project or use within the project if gathered previously and advise on the safe, secure and compliant management and use of real data. The role of the Ethics Team is to review deliverables from the ethics point of view, and 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.



*Figure 3: Key actors in SHAPES Ethics Management*

### 3 EAB members’ recruitment and tasks’ establishment

#### 3.1 The role of the EAB

As indicated in the SHAPES project proposal and SHAPES Grant Agreement, the EAB is generally responsible for providing advice in any circumstance in which project activities might potentially involve Ethics, Privacy and relevant legal implications. The EAB’s opinion can be requested by the Coordinator or WP Leaders or delivered motu proprio as result of WP8’s research ethical monitoring. (SHAPES 2019).

No compensation for the members of the EAB is provided for in the SHAPES budget. However, the cost incurred by EAB members for attending meetings will be reimbursed. For this reason, the EAB’s role will be limited to the provision of advice upon request on specific issues as they emerge and examination of controversial questions. Monitoring activities are excluded from the responsibilities of EAB, since they are the responsibility of the WP8 team.

An annual meeting (either face to face or telco) will be organized once a year.

The role and tasks of the EAB members vs. working practices are summarized in the table below.

*Table 4: Tasks of the EAB*

Task	Annual meeting	Add Hoc telco’s or emails	Individual working
-Advice on ethics deliverables	X		X
-Advice on specific ethical questions and regulatory frameworks	X	X	X
-Reports to SHAPES project and to EU commission	X		X

We can estimate that members of the EAB will allocate their time to SHAPES ethics minimum 10 days during the whole project in years 2020-2023.

Key documents on which the EAB will be asked to provide advice are SHAPES deliverables of the WP8 (see the table below).

*Table 5: Ethics Deliverables in SHAPES project*



Deliverable		Focus and Contents	Templates and Frameworks
Set up of Ethics Advisory Board	M4	Members and working practices of Ethics Advisory Board	
Baseline for SHAPES Project Ethics (D8.2)	M6	Provides the guidelines and templates for the research integrity and for the ethics management of the SHAPES project.	<ul style="list-style-type: none"> <li>-Consent</li> <li>-Information sheet</li> <li>-Privacy notice/ policy</li> <li>-Ethical self-assessment of each WP</li> <li>-Ethics compliance check of each deliverable</li> </ul>
SHAPES Ethical Framework (D8.4)	M7 and M18	<p>Provides ethical and legal requirements for the SHAPES solution. (technology and services, user processes and training, business/governance and ecosystem models).</p> <p>Legal frameworks for Smart and Healthy Ageing and for Privacy and Data Protection will be investigated more in detail later on in separate deliverables D8.3, D8.11 and D8.12.</p>	<ul style="list-style-type: none"> <li>-Ethical requirements</li> <li>-Ethics compliance check for each deliverable</li> <li>-Code of Conduct (version in M18)</li> </ul>
SHAPES Data Management Plan (D8.13)	M6	<p>Provides Data Management Plan for</p> <ol style="list-style-type: none"> <li>1) SHAPES solution (data processed on the SHAPES platform)</li> <li>2) SHAPES R&amp;D process (research data collected and processed during the SHAPES project).</li> </ol>	<ul style="list-style-type: none"> <li>-Data lifecycle management</li> <li>-Data processing descriptions</li> </ul>
Regulatory Frameworks for Pan-European Smart and Healthy Ageing (D8.3)	M42	Elaborates more in detail 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 the privacy and data protection regulation more in detail (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 Data Protection Impact Assessment (DPIA)
Privacy and Ethical Risk Assessments (D8.8 and D8.9)	M12 and M24	Analysis 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.)	Societal Impact Assessment (SIA)

### 3.2 The process and criteria used for EAB members’ recruitments

According to the EU guidelines it is essential that members of the EAB are external to the project and to the host institution, as well as totally independent and free from any conflict of interest (EU 2019). On the other hand, SHAPES GA has outlined that the EAB has both external and internal members. Therefore composition of the SHAPES EAB was discussed in WP8 tele-conferences and with the Coordinator. With regard to the external members, it was suggested that one should come from industry, one from the regulation sector, one from the user sector, and one from the academic sector, in order to mirror the stakeholders involved in the project. The role of the internal members is to be part of the ethics review but also, to inform the external partners of the background and context of the project without prejudicing their views

The recruitment of the external EAB members has entailed a collaborative process within the remit of WP8:

- (1) All the partners in SHAPES were asked to propose suitable persons for EAB either from their own organisations, from relevant stakeholders or from outside partner organizations during the kick off meeting in November 2019 and during the WP8 telco in January 2020. 8 proposals were received.
- (2) At the same time, efforts were made to identify the required competences of the members so that all ethical dimensions of the SHAPES project could be covered. The key tool here was SHAPES GA, but also ethical risk assessment conducted

during the first months of the SHAPES project in collaboration with partners (see table below)

*Table 6: SHAPES Ethical Challenges and other criteria for EAB members*

<b>Ethical challenges</b>
<b>R&amp;D process (&gt;research integrity during the SHAPES project)</b>
-R&D challenges with the older people (including consents', methods to be used...)
-Data management and openness of the research data
-Incidental Findings during the research (both on level of an individual and level of an organization or community)
<b>Ethical features of the SHAPES solution (&gt;ethically, legally and societally sustainable SHAPES)</b>
-Older people as end-users and co-creators of ecosystem of services
Agreements (with end-users of several services, with service providers ,with other actors)
-Challenges with the technology in general (including the evolution/revolution)
-Challenges and possibilities of AI and robotics
-Data management on the SHAPES platform & ecosystem
-Privacy and Data protection: GDPR and data subject's rights in practise
-GDPR and organizational responsibilities in the SHAPES ecosystem (after the project)
-Data & Cyber Security (both personal data and other)
-The composition of the ecosystem, moral division of labour in H&C - and the future use of SHAPES after the project (including political perspective)
<b>Specific challenges with the pilots</b>
Managing the collaboration with the end-users participating both in the research and using the SHAPES platform
Privacy and Data protection during the pilots where the systems are still on the development phase
Incidental findings during the processing of SHAPES data on SHAPES platform
<b>Other criteria</b>

Independence of the person (coming outside the partner organizations)
Person coming from south Europe
Person coming from middle Europe
Person coming from North Europe
Person coming from Industry/business
Person coming from regulation sector
Person coming from user sector
Person coming from academic sector

### 3.3 Members of the EAB

Table 7 shows the external and internal members of the EAB. If one or more members become unavailable to participate, there will be a substitution of the member of the EAB. This will be agreed together with SHAPES partners. In addition EAB can also suggest maximum 1-2 new member if needed from the viewpoint of ethical expertise.

Table 7: Members of the SHAPES Ethics Advisory Board

<b>External Members</b>
Liisa Holopainen Lawyer, Privacy and Cyberlaw Team Lead, Nixu Ltd.
Alberto Alemanno Jean Monnet Professor in EU Law and risk regulation at HEC Paris, Global Clinical Professor of Law at New York University School of Law, and Visiting Professor at the University of Tokyo, School of Public Policy and at the College of Europe
Dr. Eduard Fosch University of Leiden: Marie Skłodowska-Curie Postdoctoral Researcher at eLaw-Center for Law and Digital Technologies
<b>Members coming from partner organizations networks</b>
Dr. Elizabeth Mestheneos UK trained sociologist and independent social researcher who has primarily worked through the Sextant Research Group in Athens since 1991, undertaking a wide range of EU funded research projects. She is the Greek Council Member and elected Vice President on the Executive of the AGE-Platform.
<b>Members coming from partner organizations</b>
Gerald Walther Fraunhofer Institute for Technological Trend Analysis
Sari Sarlio-Siintola



SHAPES Ethics Manager, WP8 leader
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Nina Alapuranen
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SHAPES Data Protection Manager
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### 3.4 Declaration of Interests

EAB members have to declare potential conflicts of interest. Where issues are discussed that may involve a conflict of interest, the affected member shall recuse herself/himself from the discussion. Conflicts of interest will be noted in the minutes of the relevant meeting.

### 3.5 Relationship with the SHAPES

The Ethics Manager coordinates communications regarding requests of the EAB. The EAB may recommend Ethics Manager to review, monitor or audit specific aspects of the SHAPES innovation actions. The EAB may also communicate directly with individual researchers and developers of the SHAPES solution, and should enjoy open access to communication about the project. The EAB has the right to access all relevant material of the SHAPES project that is available on TEAMS. The guiding principle in relation to the relationship with the whole SHAPES Consortium is that of transparency. Advisory status of the EAB recommendation implies that individual researchers and the consortium retain their legal responsibilities.

EAB members are subject to a confidentiality agreement signed with the coordinator.

## 4 Leadership and internal decisions

### 4.1 Chairs of the EAB

The EAB has a Chair and a Vice Chair. The EAB will elect its Chairs from among its members (Please note that this represents a change compared to the original plan in GA according to which the Ethics Manager is the chairman) (see also EU 2012).

The tenure of the chairs is two years, renewable for a further two years. The Chairs have the following roles:

- Organising representation of the EAB at annual and ethics reviews
- Organising the working structure of the EAB if needed (e.g.thematic groups)
- Communicating relevant information to the EAB members
- Working with the Ethics Manager and the Ethics Management team in planning and carrying out meetings, agendas etc.

## 4.2 Attendance

Meetings of the EAB will be attended by:

- EAB external and internal members
- SHAPES Project Management Board directors or members (where appropriate)
- Further invited participants (where appropriate)

## 4.3 Communication

The EAB uses an electronic mailing list to communicate relevant information to all of its members. All members should be kept up to date electronically and should receive SHAPES dissemination materials, such as newsletters.

## 4.4 Meetings

The EAB will have Annual Meeting each year. The meeting will be organized in connection/conjunction with other SHAPES meetings (if possible), or as a virtual Zoom meeting.

The EAB Chairs will additionally have *ad hoc* teleconferences with the Ethics Manager and Data Protection Manager when needed. EAB Chairs can also be invited to attend WP8 monthly telcos when appropriate.

All EAB meetings will be based on an agreed agenda to ensure efficient decision-making. Relevant documents should be circulated beforehand to allow for adequate preparation.

# 5 Conclusions

This document has provided all the basic information in relation to the composition of the EAB for the SHAPES project, as well as the description of the working practices and tasks of the EAB. The EAB has set up for the purpose of supporting the SHAPES Project. It is a consultative body which will ensure and improve the high ethical standard and the quality of whole project and to support the consortium on ethical issues arising. Revision of the deliverable can be done if needed.

## 6 References

SHAPES Grant Agreement (2019).

European Commission (2012). Roles and Functions of Ethics Advisors/Ethics Advisory Boards in EC-funded Projects. December 2012.

European Commission (2019). How to complete your ethical self-assessment. European Commission February 2019.