Mobility as a Service in a multimodal European cross-border **Corridor** (**MyCorridor**)

Deliverable 9.2

MyCorridor Ethics Manual

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The MyCorridor project consortium consists of:

No.	Name	Short name	Country
1	NEWCASTLE UNIVERSITY	UNEW	UK
2	ETHNIKO KENTRO EREVNAS KAI TECHNOLOGIKIS ANAPTYXIS	CERTH	EL
3	OSBORNE CLARKE LLP	OC LLP	UK
4	WINGS ICT SOLUTIONS INFORMATION & COMMUNICATION TECHNOLOGIES EPE	Wings ICT	EL
5	SWARCO MIZAR SRL	SWARCO MIZAR	IT
6	EFARMOGES EXYPNOU LOGISMIKOU KYKLOFORIAS & METAFORON AE	INFOTRIP	EL
7	CHAPS SPOL SRO	CHAPS	CZ
8	HACON INGENIEURGESELLSCHAFT MBH	HACON	DE
9	MAP TRAFFIC MANAGEMENT BV	MAPtm	NL
10	VIVA WALLET HOLDINGS - SOFTWARE DEVELOPMENT SA	VivaWallet	EL
11	AMCO OLOKLIROMENA SYSTIMATA YPSILIS TECHNOLOGIAS ANONYMI VIOMICHANIKI KAI EMPORIKI ETAIRIA	AMCO	EL
12	TOMTOM DEVELOPMENT GERMANY GMBH	TOMTOM	DE
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Abbreviation List

Abbreviation	Definition
Ax.y	Activityx.y
CAD	Computer-Aided Drafting
C-ITS	Cooperative Intelligent Transport Systems
DMP	Data Management Plan
EB	Ethics Board
ECIM	European Cloud for Intelligent Mobility
EGE	European group on ethics in Science and New Technologies
EIP-AHA	European Innovation partnership on Active and Healthy Ageing
EU	European Commission
FMEA	Failure Mode Effects Analysis
GDPR	General Data Protection Regulation
ICT	Information and communications technology
IT	Information Technologies
ITS	Intelligent Transport System
LifeSTech	Life Supporting Technologies
MaaS	Mobility as a Services
MoU	Memorandums of Understanding
Mx	Monthx
OECD	Organisation for Economic Co-operation and Development
PhD	Doctor of Philosophy
QoS	Quality of Service
R&D	Research&Development
RTD	Research and Technological Development
SES	Socio-Economic Status
SMS	Short Message Service
UI	User Interface
UPM	Universidad Politécnica de Madrid
V2X	Vehicle-to-everything
WP	Work package

Executive Summary

The current Ethics Manual defines the ethics code of conduct of research within MyCorridor. Within this document, the key ethical and legal issues will be identified and a relevant project policy towards examining these issues will be developed.

This document is an update of the first version of the Ethics manual, namely D10.1: "POPD – Requirement No.1" and aims to be a reference and living document throughout the whole duration of the project with respect to ethics issues.

Key updates in D9.2 with respect to the D10.1 emerge from the feedback regarding local regulations, legislation and practices obtained by the questionnaire on Ethical and Legal issues filled in by the project pilot site leaders.

With reference to the deliverable D10.1, the following activities have been carried out:

- The Ethics Board synthesis has been revisited and the re-appointment of nominated persons has been realised, if required. The external expert that will be consulting MyCorridor Ethics Board has been also defined and engaged.
- The detailed data privacy policy – across all phases of the project; user needs, development, pilots – has been tackled with in WP2: Open Cloud System Architecture and reported in D2.1: Data management plan.
- The MyCorridor Questionnaire on ethics and legal issues (Annex 1) has been revisited in collaboration with A7.4: "Operational, equity and legal issues including security and privacy" and has been used to collect national guidelines and legislation based on previous project experiences. The revisited form and the aggregated responses from test sites on local regulations, legislation and practices have been included in the current document (see chapter 5 and Annex 1)
- The Ethics Controlling Report has been developed. Through that, the test sites will report level of compliance to the Ethics Code of Conduct of Research. The form has been included in the current document (see Annex 2).
- The legal context of incentives, the Informed Consent form (and any adaptations that may arise), the way that will be provided and signed by all types of participants, the ethics risk assessment first complete round and the overall Ethics Policy of the project has been revised and confirmed.
- The Risk Assessment and Management analysis performed in the previous phase of the project and reported in the D10.1 (POPD Requirement No.1) has been revised by the pilot project leaders and largely confirmed.

This deliverable is a source of reference material for each of the partners. It ensures that all partners have knowledge of the initial test campaign strategy for the Pilots implementation as well as data treatment.

The MyCorridor project targets citizens using public and private transport including citizens' barriers due to low digital literacy and travellers with motor or sensory limitations. MyCorridor will include all potential types of users coming from diverse backgrounds and travel patterns and preferences with the ambition to offer tailored services to each specific user group (e.g. older people, people with disabilities,

commuters, business travellers, tourists, etc.) and even to individualise services according to user profile and history of use. Thus, the project by definition will -in most cases- involve travellers that use public and private transport and commuters with the general use of those terms.

As such, MyCorridor will thereby empower users towards active and independent travelling, but, also, socially included living. While the trends and developments of the last decades tend to be inclusive and such implementations have given rise to many positive developments, concerns about the use of these tools, services, and in general technologies, in transport can be summarised as following (adapted from opinion 13 from the European group on ethics, EGE):

- The pervasiveness of a technology which many people do not understand and have difficulty to incorporate in everyday daily living activities such as transport/commuting which already might be.
- The lack of transparency of the work of other parties necessarily involved such as IT systems' and control centres' operators, service providers and other involved providers (e.g. vendors) and their effects on the provider/traveller relationship (i.e. both commercial and socio-economic related).
- The difficulty of respecting privacy and confidentiality when third parties may have a strong interest in getting access to electronically recorded and stored personal mobility and transport mode use data.
- The difficulty in ensuring the security of shared personal, localisation, service-use data.

Therefore, MyCorridor Consortium commits to the following:

- Interoperable services, tools, and architectures create the potential for the free circulation of personal travelling data, across local, national and professional borders, giving such data an enhanced European dimension.
- The principles of the European Convention of Human Rights, the rules of the Convention of the Council of Europe for the protection of individuals with regard to automatic processing of personal data and especially the European Directive 95/46/EC as repealed and replaced by the General Data Protection Regulation (Regulation (EU) 2016/679), for the protection of personal data will be strictly followed when addressing the ethical questions of MyCorridor.

MyCorridor project is compliance with any activities concerning to Ethics Review i.e. activities that would invoke concern around ethics in terms of compliance with ethical rules and standards, relevant European legislation, international conventions and declarations, national authorisations and ethics approvals, proportionality of the research methods and the applicants' awareness of the ethical aspects and social impact of their planned research. It is highlighted that in Greece all testing activities have to be approved by local research ethics committee as well as in Austria to the Data Protection Authority. This approval, as well as any others raised in the lifespan of the project, will be requested and attached to Pilot Plans Deliverable (D6.1).

Users will be actively involved in A1.1 (Survey of traveller behaviour and preferences) focus groups as well as in the Pilots of the project. Pilots in MyCorridor will be conducted in 6 pilot nodes across Europe in two rounds (from M18 to M22 and from M28-M33 respectively). In the first round of the Pilots, internal developers and service providers and travellers will be recruited by the project, whilst in the second

round, instead, external developers and service providers will be also involved together with real life travellers that will be not specifically recruited by MyCorridor though they will be certainly incentivized to use the MyCorridor one-stop shop. It is stressed that all MyCorridor users that will be recruited by the project will be able to give Informed Consent. But also those that are going to be involved in real-life pilots, we will be asked to provide Informed Consent (in digital way through the Terms & Conditions of the services they will use).

In specific, all types of users will be informed that they are going to be part of research tests and will also be informed on the way that their personal and performance data will be treated by the project. To assure continuous monitoring and control of the project, an Ethics Board has been established, led by SWARCO that is acting also as the Quality Manager of the project, including among other Local Ethics Representatives by the test sites and the cross test entities.

The relevant ethical aspects that have been analysed in this document are mainly related to the ethical and safe conduct of pilots with participants and the proper use of the collected data. More specifically, **Chapter 1** introduces the purpose and intended audience of the current document as well as the interrelations to other project work items, **Chapter 2** summarises the key ethical issues of MyCorridor concerning the control methodology that will be applied respectively in the project, **Chapter 3** describes the synthesis and role of the Ethics Board, **Chapter 4** refers to the gender issues of the project, **Chapter 5** summarizes the results obtained by MyCorridor Questionnaire on Ethics and Legal issues filled in by the project Pilots, **Chapter 6** is the main chapter of the document providing the Ethics Policy of the project across the different aspects, **Chapter 7** deals with communication issues with participants, and **Chapter 8** concludes the document describing the main outcome of the Deliverable, next steps and future updates. Finally. **Annex 1** provides MyCorridor questionnaire on Ethics and Legal issues used to provide the means for collecting local regulations and practices from the participating test sites; **Annex 2** shows the template of the MyCorridor Ethics Controlling Form that will be completed by all partners who conduct pilots before the pilots take place and after to check compliance; **Annex 3** gives a summary of the international and European instruments in the field of data protection; **Annex 4** provides the Informed Consent form and **Annex 5** reports the results on "MyCorridor questionnaire on Ethics and Legal issues " filled in by each Ethics site board.

1 Introduction

1.1 Purpose of the document

This is the deliverable report for MyCorridor project Work Package 9, D9.2: MyCorridor Ethics Manual, as required by the project's Grant Agreement number 723384. It defines the ethics policy and code for carrying out research and development in the MyCorridor project.

According to the minutes of the kick-off meeting held on the 8th and 9th of June 2017 and upon the agreement of the P.O., the deliverable D9.2 has been served as the update of D10.1 (POPD-Requirement No. 1) that has been submitted to the EC.

The scope of this document is to create the ethical framework and policy of the MyCorridor project taking into account ethical guidelines and legislation and, specifically, to define the restrictions and constraints of potential participants contacting and testing with real life users the services of MyCorridor. The ethics principle will be primarily applied to the management and execution of Pilots (WP6). However, ethics and data protection legislation, guidelines and principles have to be followed much earlier, during focus groups surveys (WP1 - Defining a disruptive MaaS culture) oe even when the partners are defining the different components and elements of the whole MyCorridor system architecture (WP2).

Furthermore, the ethical principles reported in this document have to be applied also for the subjective data, which will be collected by the project partners also during focus groups and surveys in the context of A1.1 "Survey of traveller behaviour and preferences". 6 focus groups with participants from urban locations in all the countries represented in the planned pilots (one per site) will be run to collect data on localisms and similar specific aspects directly by the users. The questionnaires to be used to this end and the respective data collected via the focus groups will be reported in D1.1 "MyCorridor Use Cases". Data management aspects are described in the D2.1 – Data management Plan and following updates.

1.2 Intended audience

The goal of this manual is to compose an Ethics Guide for all the researchers within MyCorridor and it is a living document. As the information flow is constant, multi-dynamic and layered, it is imperative to define early in the project the overarching ethical principles governing all activities within MyCorridor project including the pilots conducted during the project. Therefore, a dynamic approach is required with regards to application of Ethics principles across various activities within the project. As such, this document is valuable (though perhaps in different ways) for the following user clusters:

- WP1 focus groups' participants and research teams involved;
- Consortium members and most importantly those being involved in testing, data management (of the MyCorridor system flow but also of the pilot data), treatment, analysis and reporting, as well as communication;
- Partners involved in the development of engagement, incentivisation and recruitment strategies; to ensure ethics code of conduct are considered and applied;

- The Ethics Board (both internal and external members).

Apart from that and being a public document, this is supposed to serve also as an Ethics Guide for relevant service-oriented projects moving in the field of Mobility as a Service.

1.3 Interrelations

Ethical Issues in MyCorridor will be scrutinized in close synergy with data management, pilot and legal issues activities, namely A2.5 (Data management, reliability and QoS), WP6 (Pilot realisation and impact assessment) and A7.4 (Operation, equity and legal issues including security and privacy) respectively.

Ethical Issues will be also applied for Users involved in A1.1 (Survey of traveller behaviour and preferences) focus groups.

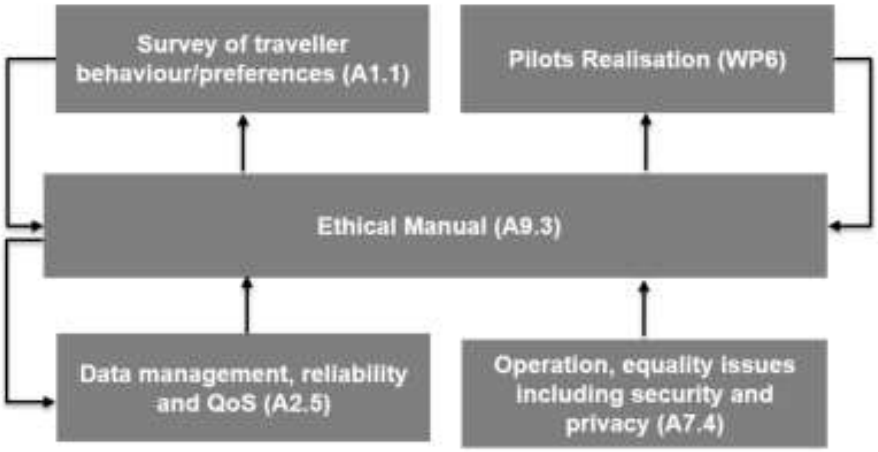

Figure 1: MyCorridor Ethical issues interrelations.

2 Ethical Issues & Ethics Control Methodology in MyCorridor

MyCorridor is a complex project with ethical issues related to security, privacy and interoperability. Each phase of the project will be addressed accordingly from the project concept development to the project closure.

Core ethical issues within MyCorridor are related to:

1. Data privacy protection, confidentiality and transparency.
2. Informed consent.
3. Incidental findings.
4. Transparency of the collected data management by the final system and during its pilots.
5. IT-Security and identity management.
6. Risk assessment (Insurance).
7. Delegation of control.
8. Incentives (Financial inducements, etc.).

A first version of the MyCorridor Ethics issues has already been defined in the deliverable D10.1: "POPD – Requirement No.1" (submitted to the EU by M3). The current Ethics Manual cab be regarded as an updated of the previous version where the following changes occurred:

1. Concerning the Ethics Board, Andrea Frisilla (IRU) and Iannis Ntilis (VivaWallet) has been re-appointment for the cross-border site.
2. The external expert of MyCorridor Ethics Board (María Fernanda Cabrera-Umpiérrez) has been defined and engaged.
3. Particular attention has been paid to enhance the Ethical Manual with legal aspects, that is: the "MyCorridor Questionnaries on Ethics and Legal issues (Annex 1) used for national data collection as well as the "Informed Consent" (Annex 4) has been revised from the legal point of view by OC; a specific paragraph has been added on Legal issues (see session 6.7).
4. The " MrCorridor Ethics Controlling Form" has been defined (Annex 2).
5. National guidelines and legislation on ethics and legal issues have been collected using the above mentioned questionnaire (Annex 1). The outcomes derived by the Pilot project leader interviews have been analysed in order to investigate the impact on the project ethics policy previously defined (see paragraph 5.6).

It is possible that during the course of the project additional ethical issues will be identified.

The management of all related issues will be carefully investigated within WP10: "Ethics requirements" in conjunction with A 9.3: "Quality Assurance and Ethical Issues". Ethics issues will be managed in the project by the **Ethics Board** that is presented in the following section.

The first version of the Ethics Manual was the document, namely, D10.1: "POPD – Requirement No.1", whereas the second official version is the current document, titled D9.2: "*MyCorridor Ethics manual*" (due by Month 6). If required, more updates of the Ethics Manual will be released (before or after the Pilots)

and will be annexed officially in the Pilot Deliverables of WP6 - Pilot realisation and impact assessment (D6.1 – Pilot plans framework and tools and D6.2 – Pilot results consolidation). The most updated version will guide all pilot related activities. Each version is communicated to the Ethics Board to ensure meaningful communication and ethics management across the project.

The **Ethics Control Methodology** of MyCorridor is dealt with in this document (D9.2), where all the relevant legislation and ethical consideration on European and local pilot site level are summarised. The local ethics practices and regulation have been collected through the form that is attached in Annex 1 of the current document (Annex 1: MyCorridor Questionnaire on Ethics and legal issues). MyCorridor Questionnaire on Ethics and legal issues has been revised in collaboration with A7.4: "Operational, equity and legal issues including security and privacy" partners.

The main parts of the questionnaire are the following and cover major aspects related to ethical conduct:

A. Participants and informed consent: Partners were asked to describe the existing procedures and guidelines related to interaction and treatment of participants and the informed consent process.

B. Ethical control instruments: Description of regional, national ethical control bodies, committees, Data Protection Authorities, etc.

C. Privacy: Description of Data Protection Acts, principles, legislations, procedures, etc. as well as allocated / responsible partners.

D. Safety: Description of health and safety regulations and each institution/ company/ region, etc.

E. Risk assessment: Description of risk assessment strategies applied at each institution

In addition, the template to accommodate the **Ethics Controlling Reports** has been prepared (see Annex 2). Ethics Controlling Reports will serve as control means during the project Pilots that will be executed in two rounds. The Ethics Controlling Reports will aim to depict up to which extent the ethical policies defined in the project have been followed/covered throughout the project activities (mainly the evaluation activities). It will be completed before and after each pilot round by the local ethics representatives and will be provided to the Ethics Board. The relevant results, which will emerge before and after each Pilot phase, will be documented in annual reports as well as Deliverables 6.1: "Pilot plans framework and tools" and 6.2: "Pilot results consolidation", the release of which is scheduled for Month 12 and 33 respectively.

The main parts of the Ethics Controlling Reports are the following:

A) ***Participants and informed consent:*** Partners were asked to describe if they have obtained participants' consent and the process put in place to have it.
B) ***Ethical control instruments:*** Description of regional, national ethical control bodies, committees, Data Protection Authorities, etc. to be applied.
C) ***Privacy:*** Description of Data Protection Acts, principles, legislations, procedures, etc. as well as allocated / responsible partners adopted in the project to be applied.
D) ***Safety:*** Description if pilot implementation has been evaluated.
E) ***Risk assessment:*** Description of risk assessment strategies applied.
F) ***Reimbursement:*** Description of reimbursement procedures at national level.

The Ethics Board has been established in the project and revised as well as some re-appointment has taken place as of the previous version of the Ethics Manual (see following section of this Deliverable). It is, chaired by SWARCO, with the tasks to prepare the different versions of the Ethics Manual of the project, the accompanying documents (like the templates on legal and ethical issues, the informed consent form, the controlling reports), to monitor the compliance of the project activities and outcomes according to the guidelines and policies reported in the Ethics Manual and, if needed, to intervene in order to modify activities and documents accordingly. In specific, the role of the general supervisor, coming from SWARCO, chairing the Ethics Board will be to oversee all relevant issues and to train those responsible for the pilots on how to abide with the recommendations of the MyCorridor Ethics Manual.

In each pilot site of the project, ethical and legal issues will be supervised by one responsible person on local level that will carefully investigate the upholding of the ethical issues.

It should be stressed that Ethics Issues in MyCorridor will be scrutinised in close synergy with data management, pilot and legal issues activities, namely A2.5 (Data management, reliability and QoS), WP6 (Pilot realisation and impact assessment) and A7.4 (Operation, equity and legal issues including security and privacy) respectively.

3 Ethics Board

As previously mentioned, an Ethics Board (EB) has been established in MyCorridor to tackle all relevant issues of the project. In specific, the MyCorridor EB has the duty to:

1. Ensure that the planned evaluations and tests – but also research activities- as well as the Ethics Policy of the project through Ethics Controlling Reports.
2. The Ethics Board will ensure the project's Ethics policy complies with relevant European and national regulations, guidelines and legislation; therefore, all updated versions of this Deliverable must be communicated to the Ethics Board members.
3. Resolute any potential ethics related conflicts and mitigate the (relevant) risks that might arise during the project.

Furthermore, the local ethics representative at each pilot site has the responsibilities of:

1. Protect private and sensitive information and ensure that participants will not be harmed during the pilots. Collected data will be anonymous and treated as confidential.
2. Respect participant's free will and treat them as intelligent beings, who decide for themselves about any type of gathered data that are indeed outcomes of their participation.
3. Inform in full and train the Local Ethics Representatives (see below) about how data will be collected, processed, shared, and disposed before signing the consent form (data management work will be realised in WP2: Open Cloud System Architecture and will be detailed in D2.1: Data management plan for Month 6 of the project).

In general, the EB works for implementing and managing the ethical issues of all procedures in the project, ensuring that all Partners are complying with the MyCorridor ethics code of conduct of research (and its official updates). This body is responsible also for the updates of the Ethics Manual; the official one is the current document, but more may emerge if needed.

As mentioned, among the EB roles is the resolution of any potential ethics related conflicts and the mitigation of risks that might arise. If a situation arises, then a decision will be centrally reached, in collaboration with the site where the problem exists and a solution will be found and communicated. The resolution of any ethical related emerging issues will be dealt first by the local site responsible and, if necessary, the issue will be discussed with the WP6 pilot manager. In case there is the possibility for the situation to affect the work carried out in several packages/domains of the project, then it will be addressed by the MyCorridor Ethics Board. Regardless of the level of involvement, the central Ethics Board will be informed by any arising issues, even if they are happening - and being resolved – at the local sites they firstly have arisen.

The EB will be also responsible to tackle the ethics related risks that will arise during other research and development activities of the project as an input to the horizontal risk management of the project, in A2.4 - Risk Assessment (see more in section 6.10 of the current document).

Different levels of ethics management ensure time-efficient addressing of issues and risks during the lifetime of the project (e.g. management of local legal issues, correct private data management and

handling) especially given the big number of services that will be integrated in the MyCorridor platform that is quite complex in notion and functioning itself, but, also, given the complexity of the whole operation being cross-border, real life, multi-stakeholder, encompassing all types of transport services, big numbers of real life travellers and specially recruited travellers both, running for long periods of time.

The Ethics Board consists of the **Ethics Management Panel** and the **Local Ethics Representatives**.

The project's **Ethics Management Panel** is composed of one external member, the Coordinator, the Technical & Innovation Manager, the WP6 Pilots leader and is led by SWARCO (Ethical Manager), that is serving also as the Quality Manager of the project. The Ethics Management Panel will supervise the ethical activities of the project and the **Local Ethics Representatives** coming from the 6 pilot nodes of the cross-border corridor (plus 3 representatives from the cross-site partners; Tom Tom, VivaWallet and IRU).

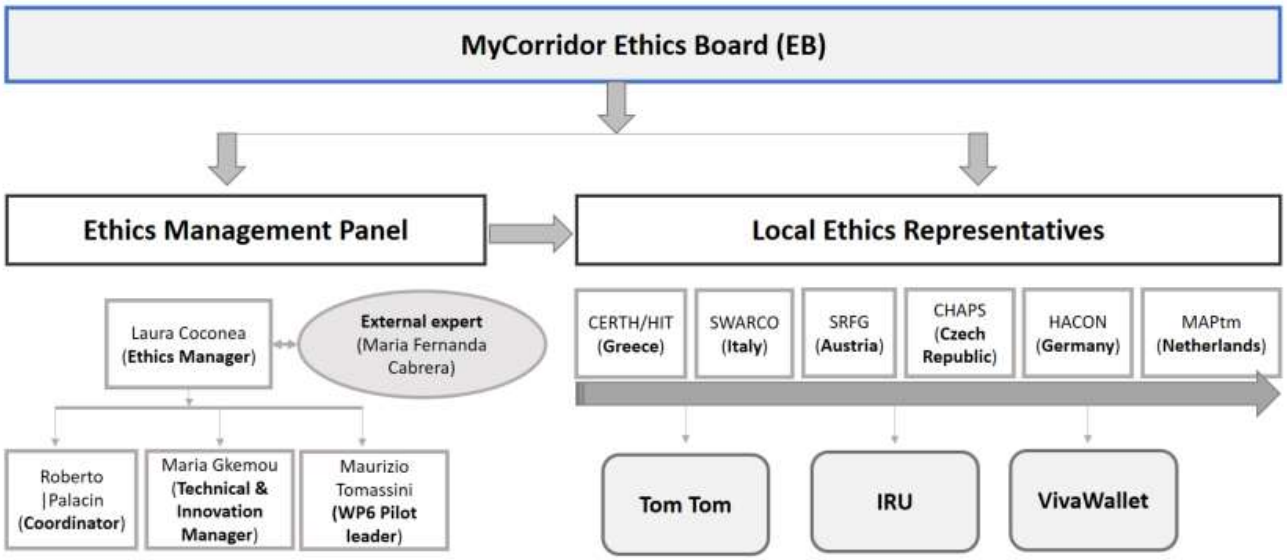

Figure 2: MyCorridor Ethics Board.

Local Ethics Representatives will be the main contact point for any ethics related issues (e.g. submission of research/test protocols for approval, by the Institutional/National Ethics Committees, GDPR, etc.) from the pilot site point of view. Their role will be to comply with the MyCorridor Ethics Code of Conduct of Research and report back after each pilot round by means of an **Ethics Controlling Report** (see Annex 2) across all issues that will be defined by the Ethics Management Panel and will tackle user involvement, ethical and data protection issues. In addition, one of the main tasks of the nominated persons will be to co-ordinate and be responsible for obtaining approval by the local/regional/institutional ethics committee before any pilot related activities take place (e.g. even before recruitment starts) - if needed. Any required or requested authorisations and approvals remain official project documents at any time and they will be annexed in D6.1: "Pilot plans framework and tools".

On the other hand, the Ethics Board will scrutinise the research, to guarantee that no undue risk for the user, whether technically, or related to the breach of privacy, is possible.

As evaluations will take place in 6 countries across Europe, attention should be specifically paid to the (relevant) national/regional/institutional regulation of each country node of the corridor that goes on top of the European legislation and the compliance to it. To collect national regulation and local ethics practices, a questionnaire has been formulated and provided in Annex 1 and the results of which are reported in chapter 5.

An Ethics Site Responsible has been chosen for each pilot site (local ethics representative), who represents the country with respect to ethics issues in specific. In case the pilot site managers decide to place another person in charge of ethics, then the table below has to be updated. EB will train and monitor the Local Ethics Representatives to abide to the European and national regulation, laws, and guidelines and MyCorridor Ethics Policy. In turn, the ethics responsible person at each pilot site will train and appoint the person who will be managing and organising recruitment processes and safekeeping of participants contact details. The ethics responsible person will inform the EB of any recruitment issues and threats that may appear with regards to data protection and end-user involvement in pilots.

Training delivery (face to face, online remote, documentation sharing, etc) to the local ethics representatives will be manage case by case.

MyCorridor EB will be also closely collaborating with the WP6 pilot leader who will act as the moderator and communicator between the pilot sites and the project's EB team.

The Ethics Board is obliged to obey the national and European legislation and code of practices and has to fully support and scrutinize any plans, operational documents, and research protocols to guarantee that the Ethics policy is applied in all activities and foremost when and where users are involved. Partners should ensure timely submission of research protocols based on their previous experience with relevant bodies in order to avoid any delays in the pilot's instantiation.

The list of the local nominated persons are as follows:

Table 1: Local (and cross-site) Ethics Responsible.

Country	Partner	Nominated person
Greece	CERTH/HIT	Katerina Touliou
Italy	SWARCO	Laura Coconea
Austria	SRFG	Cornelia Zankl
Czech Republic	CHAPS	Filip Kvacek
Germany	HaCon	Daniel Schmidt
Netherlands	MAPtm	Ruud van den Dries
Cross - site	IRU	Andrea Grisilla
	Tom Tom	Pauline Baudens
	VivaWallet	Ioannis Ntilis

Their short CVs follow below:

CERTH/HIT – Katerina Touliou, acting as Local Ethics Responsible

She is an Experimental Psychologist with an MSc on Research Methods in Psychology (2002). She currently holds a research associate position at the Hellenic Institute of Transport of the Centre for Research and Technology Hellas. Main research interests: Sensory perception in drivers and riders; the role of attention and distraction in driving performance; the effect of medicines and alcohol in driving behaviour; human behaviour dynamics; development and implementation of research methodologies and experimental theories; conduction of experimental and laboratory studies including the preparation, submission and monitoring of ethical applications to regional and institutional bodies; application of advanced statistical analysis to determine human factors' effect on driving behaviour; human factors/user experience research, and usability testing methodologies specially designed for elderly and disabled. She has participated in over 20 European and national research projects. She is a Member of the American Psychological Association (APA). She holds over 60 publications in scientific journals and international conferences.

SWARCO – Laura Coconea, Chair of the Ethics Board, acting also as Quality Manager

She holds a PhD degree in Electronics and Telecommunications Engineering from Politecnico di Torino and her main interest area is what today is being called ITS (Intelligent Transportation Systems). She has been working in different fields, from Software Engineering to CAD Design. Since 2011 she joined the innovation unit of SWARCO Mizar where she mainly had to do with Management of Commercial and R&D projects (National and EU level), development of research projects proposals, business development activities, support to product development activities and involvement in standardization process at EU level, while research activities are currently focused on Cooperative ITS (V2X). From the beginning of 2017, in addition to mentioned activities, she is also tackling the challenge of guiding this unit.

SRFG - Cornelia Zankl acting as Local Ethics Responsible

She is working as an experienced project manager at Salzburg Research. She completed a diploma programme for tourism and leisure management in the University of Applied Science in Krems, Austria as well as a master programme in Environment and Bio-Resources Management at the University of Natural Resources and Life Sciences Vienna, Austria. During the past years, Cornelia Zankl worked as project manager for the Austrian NGO VCÖ-Future Mobility in the field of mobility studies. Her current focus is on Mobility-as-a-Service, automated shared road transport as well as regional mobility strategies. As project manager, she coordinates the Digibus project (https://www.digibus.at), which is the first test of an automated shuttle on open roads in Austria. Since this test includes the transport of passengers, Cornelia Zankl is responsible for all ethical issues (e.g. legal, organisational, risk management).

CHAPS - Filip Kvaček acting as Local Ethics Responsible

He is an experienced CHAPS Project Manager and Analyst. Mr. Filip Kvaček has led number of IT projects (all successfully achieving or currently approaching their goals) covering almost all areas of transport industry. Activities covered during these projects was not only the technical aspects, but also overlapping into other areas as process and product management. Originating from airline industry, Mr. Filip Kvaček also helped local airline to implement several systems and processes and also participated as a SkyTeam IT2 coordinator – managing SkyTeam alliance new member's joining processes on IT side.

HaCon - Daniel Schmidt acting as Local Ethics Responsible

He has been working as Project Manager and Consultant at HaCon since 2012. He is responsible for various R&D projects concerned with inter-, multi- and co-modal journey planning. With a diploma in Business Mathematics from TU Berlin, he used to work as research assistant at Hannover and Brunswick Universities with a focus on transport, road engineering and urban development.

MAPtm - Ruud van den Dries acting as Local Ethics Responsible

He started working at Vialis in 2007 after graduating in Traffic Engineering at the University of Breda (NHTV). At Vialis he started as a consultant for various systems supplied by Vialis, such as, Traffic Controllers, Online Traffic Modelling platforms and Traffic Data Collection. Ruud also has great knowledge of Dynamic Traffic Management from various large scale road maintenance and (re-)building projects throughout the Netherlands. In 2010, Ruud moved to MAPtm where he continued specializing in Traffic Management Systems in general and started working for several C-ITS projects (C-ITS Corridor,

Amsterdam Group and DiTCM). Extending his previous working experience on roadworks, his main focus was on creating the Dutch profile for short (mobile) and long-term road works within the C-ITS Corridor project. Another recurring subject within his projects is Social Traffic Management. His vision is that Social Media can play a large role in collecting Traffic Data and getting a better insight into traffic flows, as well as, providing a fast and reliable, in-car platform for the distributing, personalised Traffic Information. Together with the founder he is developing Livecrowd.io to become that envisioned platform.

IRU - Andrea Grisilla acting as Cross - site Ethics Responsible

He is born in Trieste (Italy) on April 30, 1984. After taking a classical and humanist training education, in 2006 he obtains his degree in International Relations and Diplomacy in Gorizia, followed in 2008 by a Master in the same field. Being elected Secretary of the Trieste and Gorizia Branches of the European Federalist Movement, Andrea Grisilla was in charge of coordinating citizenship consultations as preliminary step to the entry of the Republic of Slovenia in the Schenghen Space and the free movement across Gorizia (ITA) and Nova Gorica (SLO). In 2010 Mr Grisilla is hired as administrative manager, within the European Intermodal Association, a European organization dedicated to the promotion of sustainable transport. In 2011, he is promoted to Project Manager. During this period, he takes care of the management of several EU-funded projects in the field of intermodal transport and intelligent transport systems. Covering both passengers and goods transportation, Mr Grisilla was deeply involved in issues related to data protection (especially in single ticketing air/train), security and law enforcement (especially in hazardous goods transportation). In 2015, he moves to the Supply Network Innovation Center (SNIC) at Procter & Gamble with the role of Communication and Contracts Manager. In this position he is responsible of drafting contracts and non-disclosure agreements between P&G and researchers. From January 2016, Andrea Grisilla has joined IRU Projects as Project Officer, involved in EU-funded initiatives. At IRU Projects, Mr Grisilla is in charge of the legal and financial aspects of project management and has the responsibility of the legal and data protection issues.

TomTom - Pauline Baudens acting as Cross - site Ethics Responsible

She is a Research Project Coordinator at TomTom Berlin since the 1st of February, 2017. She has achieved a Master degree in geography and urban development focusing on Indian Smart Cities at Paris-Sorbonne University in 2016. She is currently managing several research and innovative projects in order to implement Smart Mobility services.

VivaWallet – Ioannis Ntilis , acting as Cross - site Ethics Responsible

He was born in Athens in 1983. He studied Business Administration at the University of Piraeus and he also holds a Master degree in Accounting and Finance from Durham University UK and an Mphil Degree in Economics from National and Kapodistrian University of Athens. His main interest area is Payment Systems, transactions clearance, and Data management. He has been working in different fields of economics in different firms like finance, costing, data management, budgeting, implementation of SAP ERP. He joined Viva Wallet in 2016 where he mainly had to do with business development activities, data management, development of research projects proposals. Ioannis has also experience in Greek and European research programs.

The other CV's of the EB members can be found in D9.1: "Quality Assurance Plan", with the exception of WP6 Pilot leader, namely **Maurizio Tomassini**, and of the external Expert, namely **Maria Fernanda Cabrera**, which follows below:

Maurizio Tomassini is born in Rome and holds a degree in physics. He has more than 45 years of professional experience in different fields of technology (semiconductors, lasers, environmental monitor and control, etc.). Since 1995 he is active in the transportation technology and policy. After 10 years as director of the Rome mobility Agency in 2007 he joined ISINNOVA, a consultation body very active in EC projects. He currently supports TTS Italia in several National and European projects. He has been president of POLIS in 2000-2001.

María Fernanda Cabrera-Umpiérrez is Telecommunication Engineer, with a PhD in Biomedical engineering, working as Associate Professor of bioengineering at the Universidad Politécnica de Madrid (UPM). She is the Innovation Director of Life Supporting Technologies (LifeSTech) research group, Financial Director of the universAAL IoT Coallition and for the last three years, visiting scientific at the Image and Pervasive and Access Lab in Singapore. Apart from the teaching activities, she works as project coordinator, technical and quality manager in various EU and national research funded projects.

Her field of expertise covers a wide range of applications in the domains of the ICT applied to different sectors like, health and social inclusion, including personalisation of services and content, ambient intelligence framework services, application development for mobile phones, security and data protection, user testing and accessibility of ICT. In addition, she has experience in legal issues associated to the deployment of technological solutions for health, current policies on user acceptance and gender equality policy implementation.

She is actively participating in the EIP-AHA as co-coordinator of Action Group D4 on Innovation for Age-Friendly Buildings, Cities & Environments. She is the author of more than 100 scientific papers in national and international journals in the fields of e- Inclusion and e-Health.

4 Gender Issues

Gender equality is based on equal treatment and opportunities as defined by the European and UN Policies (e.g. Council Directive 75/117/EEC) and is adapted by MyCorridor to the maximum possible extent. During the course of the project, equal gender participation is sought and maintained across the following key aspects:

1. **Gender dimension in Research and Innovation Context**: Originally, MyCorridor is not expected to affect differently the genders in their mobility behaviour overall (or in any other side aspect). However, the interfacing of MyCorridor (user interfaces, info/alert services, etc.) may prove to need customization, depending on the gender (as well as on other population characteristics, like age, type of traveller, and on possible disabilities of the users like low digital literacy or travellers with motor or sensory limitations, etc.). As such, only this part of work in MyCorridor, and after the first trials, will explore gender related issues, leading to more adequate and personalized according to gender.
2. **Gender balance in research teams**: In compliance with the EC's Strategy for equality between women and men 2010-2015, MyCorridor aims to adhere to the basic principle of equality and balanced representation between woman and men in the research and management teams of the Consortium. Indicatively and with respect to that, it is worth mentioning that the project Administrative Coordinator is Mr. Roberto Palacin (UNEW), while the Technical & Innovation Manager is Mrs. Maria Gemou (CERTH). Beyond that, looking at MyCorridor participants, it can be noticed that both women and men are involved in all levels of project work: administrative, financial, scientific and research, technical. The project will actively support a positive discrimination policy towards women researchers, aiming to achieve at least 30% women researchers participation overall. Gender monitoring will be reported in the official reporting to the EC (M18 & M36).
3. **Unconscious gender bias during evaluation**: Gender stereotypes associated with men and women having different needs, abilities and roles have been scientifically documented to lead often to "unconscious gender issues". Performance and behaviour patterns in driving and mobility tasks is not an exception. MyCorridor will carefully plan and review evaluation with users and system optimization needs in such a way, so that it will not reproduce such stereotypes lacking scientific ground. Also, whenever applicable, balanced gender distribution will be an objective during recruitment and will be recorded. Still, it should be noted that the vast majority of pilot participants in MyCorridor will come from the pool of real-life travellers that is not possible to control and as such ensure equal representation. However, for those that will be recruited, the principle aforementioned will be followed. Nevertheless, MyCorridor aims to target users in the large sense: citizens who are travellers and commuters using private and public transport modes. The substantial number of users will ensure a wide trial perspective, including: i) different countries, ii) different age groups, iii) various types of travellers and commuters, iv) various social backgrounds, v) different living and travelling arrangements and patterns, and vi) **gender balance**.

5 Summary of MyCorridor Questionnaire on Ethics and Legal Issues

As already mentioned in section 4, an Ethics Site Responsible has been identified in each pilot site, to guarantee that the pilots abide to the overall MyCorridor Ethical Policy. In this project phase, a questionnaire on ethical and legal issues, divided into different subsections (informed consent, ethical control instruments, privacy, safety, risk assessment) has been completed by each Ethics site Responsible with the aim to collected national guidelines and legislation as well as to serve as a checklist reminding the researcher to take into account all relevant ethical aspects before planning and later on conducting any experiment within MyCorridor.

From the questionnaires, it has been emerged that, in general, legal requirements on data collection depend also on national legislation. In the following paragraphs, the questionnaires results have been summarised for each its subsections and country (Italy, Greece, Austria, Czech Republic and Netherland). The project Ethics Policy has been updated respectively when applicable.

5.1 Participants and Informed consent

In all pilot countries, except Greece, test activities have not been approved by national research ethics committees.

In general, informed consent is needed to be obtained for personal data and audio records management both evaluation pilot phases as well as also for the "survey of travel behaviour and preferences" to be performed in the activity A1.1 (Survey of traveller behaviour and preferences) because data from recruited and engaged users will be collected, stored, treated, analysed and reported.

It is not envisaged to conduct pilots with individuals that might not understand the informed consent form.

The oral consent of a participant in presence of a witness is not appropriate in accordance with Italian and Austrian national legislation, while it is accepted in Czech Republic, Greece and Holland.

With reference to healthy human participants, apart from the European regulation GDPR (General Data Protection Regulation) (Regulation (EU) 2016/679) which has to be taken in account in all MyCorridor pilots countries; the following national laws have been pointed out:

1) For Italy: D.lgs 196/2003 for the protection of personal data
2) For Greece:
    a. *ν*. 2472/1997, 2819/2000, 2915/2001, 3235/2004, 3471 /2006 for the Protection of personal data collected during trials/ tests.
    b. *ν*. 927/1979, 3304/2005- Racism and *ν*. 3536/2007, 3613/2007 – Immigrants and foreigners related to the equal treatment of participants regardless their age, gender, race or minority group they belong to, ethnicity, religion, sexual preferences, disability, language and socio-economic status.

c. Legislation related to data protection and security can be found in the following links: ν.2472/1997 – Individual Protection and Personal Data treatment (http://www.dpa.gr/portal/page?_pageid=33,123437&_dad=portal&_schema=PORTAL)

3) For Netherlands: Dutch Medical Research Involving Human Subjects Act.
4) For Austria: Data Protection Act 2000 (DSG 2000), BGBl. I No. 165/1999 as amended, from May 2018 onwards the Data Protection Act 2018 will be in place. The planned activities must be submitted to and approved by the Data Protection Authority.[1]

But, in any case, the involvement of disabilities people in pilots will be done in line with the United Nations Convention on the Rights of Persons with Disabilities (described in detail here: http://ec.europa.eu/social/main.jsp?catId=1138&langId=en).

Finally, it is underlined that during all the project life all the international and European legislation and guidelines defined in Section 6.7 (about legal issues) will be taken into consideration.

5.2 Ethical control instruments

Each ethics site responsible has "Ethical controls" procedures at organization level.
No ethics controlling body are present in Italy, Greece and Czech Republic both at national level or local/institutional. While, in **Austria the** ethics committee for the province of Salzburg is located at the Paris-Lodron University of Salzburg. The Ethics Committee is responsible for the assessment of clinical trials according to the German Medicines Act (AMG), the Medical Devices Act (MPG), the Genetic Engineering Act (GTG) and new medical methods as well as applied medical research and nursing research projects according to the Salzburg Hospital Act 2000 (SKAG). Conducting ethical research on other topics needs to be requested, i.e. Salzburg Research would have to submit a request at the ethics committee if they would investigate the relevant aspects from the MyCorridor project.
In the Netherlands, the Central Committee on Research Involving Human Subjects has to be reported.

In Greece, CERTH will submit an ethics application to its CERTH Ethics committee that includes the following items: Project description, detailed pilot plan, descriptions of systems and data collected, data privacy and anonymization procedure, informed consent and all the evaluation material that will be administered. In addition, any other relevant information that does not fall in these categories but are essential for the pilot conduction is annexed. Oral consent should be obtained and relevant form is prepared and submitted for approval to the Ethics committee at CERTH.

As basic principles:

- participants must be informed and must give their authorization for their personal data management.

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1 from May 2018 onwards that obligation to reimburse DVR notifications to the data protection authority ceases however, in certain cases it will be necessary It to carry out data protection impact assessments within the meaning of Article 35 GDPR to assess the legality of certain data uses.

- the consent form must be submitted in format that is comprehensible by the participant if the person does not require a legal representative. We do not involve participants who cannot consent and need consent by the legal representative/ care provider.

5.3 Privacy

Privacy in **Italy** is dealt with according to the national law namely D.lgs 196/2003 and the European regulation GDPR (General Data Protection Regulation) (Regulation (EU) 2016/679).
In general, it is not envisaged to collect sensible personal data such as health-related information.
In addition, it is highlighted that SWARCO Mizar (Italian Ethics site representative) implements specific procedures for digital data protection according to the 2700 standards as well as for personal data management according to the ISO9001:2015 norm. Persons involved in the personal data management have been granted by the SWARCO Mizar Managing Director through a written assignment letter.

In **Greece**, personal data will be collected and stored only if participants agree to be added to the recruitment database that is not stored with any data related to project pilots and experiments. They are kept and stored separately and only one person has access to them. This information is added in the consent form. Sensible personal data (e.g. health-related information) are used only for clustering users in categories and they are not related to any other personal information because they are coded.
In addition, depending on the nature of the experiment/trial/pilot, it is envisaged to apply to the National Data Protection Authority, i.e., when we collect personal data. Official approval is required before we conduct tests. Written procedure for protection privacy is also implemented, such as: each participant is allocated with a code that does not contain and/or reveal any personal information. The allocation takes place during recruitment. Therefore, data collection for each participant is only related to the participant code and in no way to the person themselves. The recruitment officer has only access to the database and does not know which code is allocated to each person as they are randomly allocated using an Excel tool. All files are password protected and stored locally. Pilot data and personal information data are not stored together and are not accessed by the same people.
At national level, apart from the European regulation GDPR (Regulation (EU) 2016/679), data protection legislation is in force
(http://www.dpa.gr/portal/page?_pageid=33,123437&_dad=portal&_schema=PORTAL).

Privacy in the **Netherlands** is regulated by Authoriteit persoonsgegevens (for details you can see: autoriteitpersoonsgegevens.nl/en).

In **Czech Republic** there is a specific office for personal data protection, namely ÚOOÚ, to which you can registere (anyway, in case of MyCorridor experiment it is not planned to collect any data that require this kind of registration to ÚOOÚ). Written procedures for protecting privacy will be taken in place by CHAPS, as Local Ethics site representative, according to its company quality processes established in line with the ČSN EN ISO 9001:2009 norm.

In **Austria**, there is a Data Protection Authority issuing procedures/standards to be followed before performing tests with human participants and their personal / private data.

The Data Protection Act 2000 (DSG 2000), BGBl. I No. 165/1999 as amended, is the current Austrian data protection law and thus the most important legal regulation on data protection in Austria. From May 2018 onwards the Data Protection Act 2018 will supersede the current act.
Procedures in the quality management system (ISO 9001:2015), which define how sensible data are stored and who has access to that data, are in force by SRFG, as Austrian Ethics site representative.

5.4 Safety

MyCorridor tests and pilots do not involve any risks about safety. No such issue is anticipated/expected for MyCorridor project.
Safety aspects are managed in the pilot countries in line with its national regulation, for example:

1) In Italy, there is the regulation Dls 81/08 in force.
2) In Greece, an internal document exists that describes the procedure and the organizational structure of the committee for health and safety within CERTH (in Greek language).
3) In the Netherlands, it is available a checklist to establish a safe workspace on worksites, named VCA (Veiligheid Gezondheid Milieu) Checklist Aannemers.

Pilot implementation effects will be evaluated at project level.

5.5 Risk assessment

In **Italy**, risk assessment concerning breach of privacy and / or breach of safety is performed according to the national regulation Dls 81/08 and ISO9001:2015 norm. In particular, SWARCO Mizar has elaborated a document (named DURC) about safety and risk analysis. While privacy issues are managed according to the company quality procedures in line with ISO9001:2015 norm (e.g. Periodic internal Audit and corrective action). SWARCO Mizar is insured against risks as a result of breach of privacy and safety for all its employees.
In the same way, also Salzburg Research (SRFG) for **Austria** and CHAPS for **Czech Republic** are certified according to the new standard ISO 9001: 2015 and any chances and risks concerning the risk-assessment of breach of privacy and/or breach of safety are depicted in their quality management system. Salzburg Research is insured over the office of the Salzburg provincial government (liability insurance).
CHAPS has a company insurance covering this kind of risks, insurer is CHUBBS (https://www2.chubb.com/)
Maptm (the **Dutch** Ethics site representative) has never stored sensitive data in the past, so they currently have not in force an insurance against risks as a result of breach of privacy and safety.
In **Greece**, the breach of privacy exists on institutional level and not on organizational level. Breach of safety exists on organizational level (i.e. CERTH) and includes institutional practices (i.e. HIT). Employees and volunteers are insured for breach of health and safety but not for privacy only when they are within CERTH premises. Privacy protocol are applicable on institutional level. The Ethics committee and the legal department of CERTH will be involved for ethical approval.
If necessary, the legal consultation on research related activities will be contacted.

5.6 Overall conclusion and feedback to the Ethics Policy of the project

As described in this document, ethical issues under the auspices of MyCorridor are mainly concern: Informed consent, ethics control and monitoring, privacy, data management, risk assessment, the roles of the ethics advisory Board and the local Ethics Sites Responsible persons at pilot sites. These aspects have been analysed both at European and at national level, whose relevant information has been gathered throughout the questionnaire on ethical and legal issues filled in by the pilot project leaders.
As principle, whenever any national/institutional regulations are stricter than European ones and/or override them, MyCorridor activities will be carried out according to national/institutional laws.

From the collected questionnaires, the following regulations appear for the project:

- Informed consent has to be obtained also for audio records.
- Participant oral consent (even if in presence of a witness) is not applicable in Italy and Austria.
- With reference to Ethical control instruments, it has to be taken in consideration that for the pilot execution in Austria and the Netherlands, it is necessary to report project activities also to national committee (Austria: ethics committee for the province of Salzburg, the Netherlands: the Central Committee on Research Involving Human Subjects). It has also to be underlined that, even if there are not Ethical control instruments, in all the other project pilot countries, ethical controls are audited at company level; for example the Greece pilot leader (CERTH) has to submit an ethics application for approval at CERTH Bioethics committee.
- Concerning "Privacy", each pilot country has in force national regulations, which are complementary to the GDPR (General Data Protection Regulation) (Regulation (EU) 2016/679) and have to be fulfilled. The list of the national regulations for each project pilot Country has been reported in the session 5.3). In particular, it has been underlined that each pilot project country has a "Data Protection Authority" issuing procedures/standards that must to be followed before performing pilots with human participants and their personal/private data.
- Pilots have to be conducted safely and safety risks are not foreseen. However, it has to be underlined that in Italy, pilot activities (mainly concerning on-site activities) must comply with national regulation DLS 81/08.

6 MyCorridor Ethics Policy

Data privacy policy during all phases of the project – user needs, development, pilots and processing of results - will be addressed in detail WP2: Open Cloud System Architecture and will be reported in the so-called dedicated deliverable D2.1: Data management plan. Overall, the project data management plan are fully is in compliance comply with the MyCorridor Ethics policy.
The key principles are summarised in this section.

6.1 Ethics Policy in summary

MyCorridor research will be continuously monitored by its Ethics Board. MyCorridor will strictly follow the opinions of expert committees in the field (e.g. the European group on ethics (EGE) in science and new technologies). All national legal and ethical requirements of the Member States - where research and pilots are performed - will be fulfilled. Personal data of participants will be strictly held confidential at any time as well as will be processed in compliance with data protection laws. However, Data Management policy in detail is described in D2.1: "Data Management Plan". The key points of the Ethics policy that constitute the MyCorridor **Ethics Code of Conduct of Research** are the following:

- **Ethics control and monitoring**: All MyCorridor test sites and cross-test site entities that will participate in the project Pilots have nominated a Local Ethics Representative that will be supervised by the Ethics Board of the project and will be obliged to comply with the Ethics Policy of the project, the European and national/regional regulations and practices and report back to Ethics Board all relevant activities, their compliance as well as any problems that may arise respectively. The means to do so will be the **Ethics Controlling Reports**, annexed to this document (see annex 2). The aggregated responses from the test sites will be included in the pilot plans Deliverables and the annual reports. In addition to MyCorridor Controlling Report, in Austria and the Netherlands there is local ethics committee, named respectively: Ethics Committee for the province of Salzburg and the Central Committee on Research Involving Human Subjects, to which the project pilot planned activities will be submitted. In Greece, CERTH will submit an ethics application to its internal company Ethics committee.

- **Personal data protection**: Personal data will be anonymised and strictly used for project's purposes. No personal data will be centrally stored, without anonymization. No identification data will be available to pilot sites. Only one person per site (Local Ethics Representative) will have access to the relation between participant's code and identity, in order to administer the tests. One month before the end of the project, this reference will be deleted, thus safeguarding full anonymization of results. The stored data will only refer to users' age, gender and nationality (no other identifier will be kept). The user numbers will help to create and maintain anonymity. Nevertheless, stored data relates only to users' preferences for travelling and commuting and not to "sensitive personal data" such as a person's beliefs or political or sexual preferences. More on Data Management policy in detail can be found at: D2.1: "Data Management Plan".

- **Reimbursement**: All participants will be strictly volunteers. Maximum reimbursement will be up to 30€ per person, for those users that will be specifically recruited by MyCorridor, whereas for the other real-life travellers other types of incentives (i.e. discounts in services use) will be offered. In case of simpler surveys that do not require users' performance testing, 15€ and 20€ for more in-depth studies are foreseen. In general, it is not envisaged to give money to the pilot participants. Anyway, before performing pilots, the reimbursement mechanisms will be revisited by MyCorridor Ethical Boards and approved. Still, it is common to apply such small one-off payments to benefit claimants because they are treated as capital rather than income. In the cases where reimbursement incentive is foreseen, claimants (research interviewees) should be made aware of the status of the payment in opt-out letters using the following terminology: 'If you do take part in the face-to-face discussion/trial/survey, you will receive XX € in cash, as a 'thank-you' gift for your help with this study. This will not affect your entitlements to benefit in any way. However, in any case, it should be avoided to apply reimbursement in the form of incentive payment. To be able to do that, test planning and users recruitment should start early in advance.

- **Informed consent**: Those MyCorridor users that will be recruited by the project for the needs of specific pilot tests will be able to give informed consent to participate. Informed Consent is needed to be obtained for personal data and audio records management. No tests with people with any cognitive problem are planned. In the case of real-life travellers that will not be specifically recruited by MyCorridor, the informed consent will be provided to them either through the respective service providers that will inform them about the integration and the use of their service in the context of MyCorridor one-stop-shop (even if, it is not required by the existing Terms and Conditions they have already signed), or through the MyCorridor vouchers or via the MyCorridor platform itself. From a data protection perspective, we expect it will be safer to inform travellers of the integration with MyCorridor. This gives all travellers an opportunity to opt out and achieve something approximating equal treatment with the users recruited for pilot tests from whom informed consent is sought. The specific legal context and way forward regarding this issue will be defined in chapter 6.7.1 in synergy with A7.4: Operational, equity and legal issues including security and privacy.

- **MyCorridor policy on privacy, transparency, confidentiality and risk assessment and acknowledgement to the participants of MyCorridor studies**: The following issues should be explained by the supervisors of the trials to the recruited participants. If possible, this should be done in the context of training workshops to be organised before the trials' beginning. If this is not possible, all following should be explained to each participant individual before the beginning of the trials and before signing the consent form. Explanation will be in writing. In the case of real-live travellers (in the second round of tests), respective explanations will be provided through the platform. It should be noted that informed consent is a process, not just a form. Information should be presented to enable persons to voluntarily decide whether to participate in MyCorridor. The following points to be acknowledged by the users will be revisited according to the national legislation and the ethics controlling reports. Still, they constitute the first key reference points that reflect MyCorridor policy. As such, MyCorridor pilot participants should acknowledge the following points in the context of the Informed Consent and the accompanying Information Sheet in both written and oral form (Informed Consent form is provided in Annex 4.1; still the accompanying Information Sheet will be defined as soon as the concise research/text context will be available and will be annexed to D6.1 – Pilot plans

framework and tools; it will however encompass the contents denoted below):

- **General scope of MyCorridor and short reference to its objectives**.
- **Scope and short description of the research experiment**.
- **Value of participation**. The supervisor should explain in this case why the participation of the user is important, how it will assist in the research realised in the project (benefits for the project) and why the participant should consider joining this experiment as a research participant (benefits for the participant and the public in general).
- **Acknowledgement of research results**. The participants of MyCorridor studies will be acknowledged that are entitled to receive the results of the studies (they have participated in) if they wish in the specific accessible format required in each case (e.g. odt, *.pdf, html, printed, in Braille, ...). This will also serve as an evidence to them that the privacy and confidentiality issues have been respected in the analyses.
- **Tasks for each participant in the context of the research experiment**. The supervisor should explain to the participant what the exact tasks are for him/her during the trials. If applicable, specific instructions should be given orally and/or written regarding the tasks to be realised by the participant. If needed/applicable/available, a further training manual should be provided to him/her in advance (and s/he should be given the time to study them before starting). The participant should also be given the opportunity to try/play with the prototype to be tested and ask any questions before the official start of the trials).
- **Constant support during testing**. The supervisors should confirm to the participants that during the testing, they may ask whatever they need and as frequently as they wish. In addition, the details of contact persons who are able to answer questions of participants about research, rights as a research participant, and research-related injuries should be provided.
- **Risk assessment**. The project has been evaluated to present low risk for side-effects in general. The major identified risk is the risk of invoking unrealistic hopes and expectations for personal benefits in terms of improved mobility. This will be counteracted by very explicit and adequately communicated information about the limitations of such personal benefit. In general, pilot studies are run to detect side-effects before the experiment. However, MyCorridor tests will include common everyday tasks (interface with web/mobile applications for common tasks like viewing, booking, paying, etc.). Thus, none of these tests should have (side-) effects on the physical or mental integrity or health of the participant. However, given the variety of target groups (healthy, able-bodied, disabled, elderly people, etc.), all sites will review internally the appropriateness of the tests for each of the target groups and alter the tests in case it foresees incompatibilities with the situation of (one or more of) the expected participants.

  In any case, and although this is not applicable in MyCorridor, the supervisor should explain to the participants if there any kinds of harm that could be experienced during the trials and what are the measures that have been taken in order to prevent that and reduce any such chances. In MyCorridor case, and since the scheduled testing does not imply any kind of harm for the participant, it would be enough if the supervisor assured the participant for their safety and security. Also, when there are safety related issues (i.e. in-vehicle information and scenarios of use) all necessary precautions will be taken. In all

cases, the test sites will abide with the internal and/or national safety regulations applying in their case as reported in chapter 5.5. For example, in Italy, risk assessment concerning breach of privacy and / or breach of safety is performed according to the national regulation Dls 81/08. All the pilot project leader has established internal company quality assurance procedures according to the ISO9001 norms, which will be adopted to guarantee high level quality in the MyCorridor activities performance.

The oral consent of a participant in presence of a witness is not appropriate in accordance with Italian and Austrian national legislation, while it is accepted in Czech Republic, Greece and Holland. Concerning "Privacy", each pilot country has in force national regulations, which are complementary to the GDPR (General Data Protection Regulation) (Regulation (EU) 2016/679) and have to be fulfilled. The list of the national regulations for each project pilot Country has been reported in the session 5.3)

- **Deception**. No deception will take place within MyCorridor tests, except in cases that the system functionality is actually emulated. However, this cannot be considered to be any type of deception (usual practice followed in Human Factors tests) and in any case, the users will be made aware of this, before the start of the testing (in the context of "Scope and short description of the research experiment").

- **Free withdrawal**. Assurance that even if the consent form is signed by the participant before the start of the trials, the participant can change his/her mind and withdraw at any moment before the scheduled end (part of the consent forms). It should be also clarified that the consent form will be signed twice. One copy will be kept by the investigator/supervisor and the other one will be given to the participant. It will be pointed out that no penalty or loss of benefits will occur as a result of either not participating or withdrawing at any time of the experiment.

- **Acknowledgement on video/sound recording sessions and screen capturing facilities** (if applicable). It this is applicable, the participants should give their consent before the beginning of the trials (part of the consent forms). If the user does not agree to this, none of the above will take place.

- **Assurance on secure handling of private data** (data touching upon the identity and private life of the individual, therefore personal data in general, – respective statement has been included in the Informed Consent of Annex 4) and acknowledgement of the MyCorridor Ethics policy regarding that. The supervisors should clearly explain to the users that, being in line with the MyCorridor Ethics policy, the personal data that will be asked during the trials will not be permanently stored but it will be recorded only temporarily to allow statistical analysis (also to provide back to them the results of the studies). The approach to be followed in specific is the following and should be acknowledged to the participants:

    - All participants will provide the info mentioned above to a single person in each pilot site, to be stored in a protected local database (to allow contacting them further and arranging with them the sequence of the current or future tests). The contact person will issue a single Test ID for each of them. This person will not participate in the evaluation and will not know how each user behaved.

- The name, contact details (telephone, e-mail) will be kept in the database only for the duration of the project2.
- Such data will not be communicated to any other Partner or even person in each pilot site. Once the project ends, they will be deleted.
- Since personal data will be deleted after the end of the project, no follow-up studies with the same people will be feasible.
- For the statistical analysis, the answers provided by the participants will be associated with their type of impairment (if any) or travel behaviour and pattern (common origin-destination paths), age, gender, etc. However, each month, and during the project, the anonymised data will be re-sorted randomly, to mix participants' order.
- The Local Ethics Pilot Responsible will be trained (by the Ethical Board) in each test site, to monitor and guarantee that the relevant procedure is strictly followed and that all local Ethics Committee recommendations and national relevant laws are being respected.

The Consortium shall implement the research project in full respect of the legal and ethical national requirements and code of practice and will achieve that using the *Local Ethics Representatives* and the *Ethics Controlling Reports*. Whenever authorisations have to be obtained from national bodies, those authorisations shall be considered as documents relevant to MyCorridor. Copies of all relevant authorisations and approvals shall be submitted to the Commission prior to commencement of the relevant part of the research project.

The Ethics Policy of the project will be continuously monitored and updated whenever required. Starting from the D10.1, the first official revision has been performed in the context of this document and it takes into account the results collected through the Annex 1 questionnaire. Future updates will take into consideration the Ethics Controlling Reports outcomes.

MyCorridor Ethics policy will be shared with the Local Ethics Representatives in the form of guidelines to have as a guide while organising/conducting the tests. After each evaluation round, level of abidance to the Ethics Policy will be confirmed.

Finally, it should be highlighted that according to MyCorridor policy, all target end-user groups have to be sufficiently represented and be given equal opportunities for trying the MyCorridor solution, whereas gender representation equilibrium should be also reached (see more in sections 4 and 6.3).

Details on the above summary are provided in the following sections.

[2] *This is required in MyCorridor in order to strengthen the iterative nature of the project that there will be an attempt to involve the same users that will be recruited by the project to the greatest possible extent, starting from the field trials of WP1 the first year of the project until the last evaluation round towards the end of the project; therefore, it is necessary that contact details are kept as long as the project is running. Contact details are kept by only one allocated person within the evaluation team that safeguards their details and stores them separately from their results. This information will be included in the information sheet of the consent form.*

6.2 The benefit/burden balance of the research project

Besides scientific advance, the potential benefit for the travellers from the project will be social, cultural, economic and individual. Looking at the project in terms of human dignity, MyCorridor supports citizens as travellers with personalised needs and wants to move, travel, commute as autonomously and independently as efficient as possible, for as long as possible. Furthermore, adapted and personalised services and technologies enhance the possibility to participate in more complex travelling habits users who were till now relying to specific habitual travelling routines (e.g. lower digital literacy late older citizen). Access to transport modes and general mobility is facilitated, sustained and improved. Therefore, putting benefit and burden of the project on the scales, benefit preponderates.

We do declare that the research targets of MyCorridor follow Article 6 (2§) of Directive 1982/2006/EC. Therefore, MyCorridor **will not touch** any of the following fields of research:

- research activity aiming at human cloning for reproductive purposes;
- research activity intended to modify the genetic heritage of human beings which could make such changes heritable;
- research activities intended to create human embryos solely for the purpose of research or for the purpose of stem cell procurement, including by means of somatic cell nuclear transfer.

Furthermore, MyCorridor **does not** include any research involving the use of human embryonic tissue, human foetuses, human foetal tissue, other human tissues, genetic information, people unable to give consent, pregnant women, nor animals.

6.3 Target user groups

As mentioned above, the main target user groups of MyCorridor are all citizens using any land transport mode to travel and commute. As mentioned previously, the biggest part of the pilot population will be real-life travellers that will be given specific incentives to use existing services through the alternative path of the MyCorridor one-stop-shop.

This means that all types of travellers may use the MyCorridor one-stop-shop as it is happening in the real world and there can be no control over that. Through the informed consent of the travellers to the existing services Terms and Conditions and the Memorandums of Understanding between the project and the different service providers, the ethical participation of those travellers is assured.

However, apart from them, there will be two more types of users that will participate in MyCorridor pilot activities, namely the developers and service providers (transport operators, mobility service providers, content providers, etc.) that in the 2nd test round will be external and users that will be recruited specifically to execute concrete parts of the pilot plans. Those will be covering the following profiles as minimum (respecting also gender equality), though user profiles are expected to be revised in the context of WP1 (titled: Defining a disruptive MaaS culture):

1. The "**Commuter**".
2. The "**Tourist**".
3. The "**Businessman**".
4. The "**Spontaneous user**".
5. The "**Mobility-restricted**" user (e.g. user with disabilities).
6. The "**Low IT literacy user**" (e.g. elderly user).

In this case, both the developers/service providers and the recruited travellers will be asked to provide informed consent. In this context, and despite the fact that MyCorridor aims to be all-inclusive, and, as such, covers the needs of all types of travellers with varying profiles (needs and preferences), as stated above, all participants that will be specifically recruited by MyCorridor will be able to give informed consent, which means that persons with cognitive difficulties will not be recruited.

In any case, pilot sites will receive only anonymised and coded information for all participants in both rounds of the pilots, both real-life and recruited users.

6.4 Definition of partner responsibility related to ethical issues

MyCorridor open cloud system will provide out-of-the-box security mechanisms and management procedures so as to a) ensure personal (sensitive) data protection through a strict process of data collection, anonymization, harmonization and integration and b) guarantee data integrity and reliability, ensuring system's high performance operation through the exchange of the necessary information, as reported in the D2.1 – Data management plan.

In particular, the following project partner regulations related to compliance, approvals, privacy, personal information and collaboration within the project shall be applied:

- Each party shall be responsible for ensuring its own compliance with all laws and regulations applicable to its activities. Such laws include, but are not limited to, those in respect of rights of privacy, intellectual property rights and healthcare.
- Each party represents that it has all necessary third party, participant consents to permit distribution and use of the any data and any other information provided to other parties.
- Any party which provides any data or information to another party in connection to the project will not include any personal information relating to an identified or identifiable natural person or data subject.
- To this end, the providing party will anonymise all data delivered to other parties to an extent sufficient to ensure that a person without prior knowledge of the original data and its collection cannot, from the anonymised data and any other available information, deduce the personal identity of participants.
- Each party shall be solely responsible for the selection of specific database vendors/data collectors/data providers, and for the performance (including any breach) of its contracts between it and such database vendors/data collectors, (to which no other project partner shall be a party, and under which no other partner assumes any obligation or liability) and shall further warrant that it has the authority to disclose the information, if any, which it provides to the other parties, and that where legally required and relevant, it has obtained appropriate informed consents from all the individuals involved.

- Partners supplying special data analysis tooling, shall have the right on written notice and without liability to terminate the license that it has granted for such tooling to be used in connection with the project, if the supplying partner knows or has reasonable cause to believe that the processing of particular data through such tooling infringes the rights (including without limitation privacy, publicity, reputation and intellectual property rights) of any third party, including of any individual.

6.5 Data privacy protection, confidentially and transparency

6.5.1 Introduction

Data privacy policy during all phases of the project – user needs, development, pilots and processing of results - will be addressed in detail *WP2: Open Cloud System Architecture* and is reported in the so-called dedicated deliverable *D2.1: Data management plan.* The project data management plan is in compliance with the MyCorridor Ethics policy.

Privacy is the protection of a person's physical, mental and behavioural characteristics.

Confidentiality is how researchers treat participant's information to ensure that no personal information or other type of data is shared with another entity or otherwise disclosed without written informed consent by the participant.

Transparency, on the other hand, is a fundamental aspect of data collection. No data should be collected if the adopted procedures do not follow certain principles.

All individuals will be explicitly informed of the purpose for which we are collecting their personal information and how their personal information will be used. Each individual will give each pilot site collecting personal information informed consent to use that information, by completing and executing an informed consent form (as contained at Annex4).

Personal data can only be stored for as long as necessary according to the OECD and the Directive 95/46/EC as repealed and replaced by the General Data Protection Regulation (Regulation (EU) 2016/679)". Individuals have rights in relation to their personal information that they share with pilot sites, e.g. the right to request for their personal information to be deleted. Participants will be notified of these rights when granting consent for a pilot site to use that personal information. These rights will also be set out in our privacy policy available on the MyCorridor website.

All applicable legislation and regulations, including the principles of the European Convention of Human Rights, the rules of the Convention of the Council of Europe for the protection of individuals with regard to automatic processing of personal data and the European Directive 95/46/EC as repealed and replaced by the General Data Protection Regulation (Regulation (EU) 2016/679), for the protection of personal data will be strictly followed and complied with when addressing the ethical questions of MyCorridor.

6.5.2 Data Privacy Policy during Pilots

In summary, participants, and the data retrieved from them (e.g. performance or subjective responses) will be anonymised unless reasonable not to and in circumstances where the individual has given

informed consent to do otherwise. However, the following guidelines should be followed by pilot sites carrying tests with end-users:

1. Identifiable personal information should be encrypted (i.e. anonymization and coding). Otherwise ethical approval is necessary specifically for this. The stored data will only refer to users' age, gender and nationality (no other identifier will be kept). Stored data relate only to users' preferences for travelling and commuting and not to a person's beliefs or political or sexual preferences. Storing of anonymised demographic data is separate from travel preferences and pilot results adding another layer of privacy to data storage. Aggregation and consolidation efforts will be carried out by allocated evaluation members that have partial access to data and access only aggregated, consolidated and/or metadata files, as it will be defined with the project's Data Management Plan.
2. Anonymization is preserved by consistently coding participants with unique identification codes. Only one person at each pilot site will have access to personal identifiers (if any). A Test ID will be issued for each of the participants, whereas the pilot site person that will collect and issue them will not participate in the evaluation and will not come into contact with the test participants and their performance in the tests. Participants who will consent for video recording will participate in testing and their results will be used only for scientific purposes, in an anonymised manner.
3. Each individual entrusted with personal information is personally responsible for complying with this Ethical Manual and MyCorridor's privacy policy together with all applicable data protection legislation.
4. Pilot site managers must take personal responsibility for ensuring that training procedures, supervision, and data security arrangements are sufficient to prevent unauthorised breaches of data protection and confidentiality.

Important aspects of data privacy protection and processing of personal data that are accommodated for in the consent form are the following (see Annex 4.2):

- Data collection, storage and research purpose.
- Data transfer and communication.
- Data ownership.
- Data connection with personal information and separate storage.
- Commercial exploitation of data.
- Data storage duration.
- Granting access to data.
- Data supervision.

6.5.3 Transparency of MyCorridor system during Pilots

Data processing is allowed under specific transparency principles and situations as defined below:

- The participant has given informed written/oral consent;
- Is part of a contractual agreement that needs to be met;
- There is a legal obligation;
- It is necessary to be in the participant's best interests;

- There is public or official authority interest;
- Any aforementioned interest does not override the fundamental rights of participant's freedom;
- The participant may request access to data and, additionally, they may ask to delete or change data that they believe are inaccurate or incomplete. (Art. 12; Data Protection rules, see Annex 3).

Lastly, the participant should be informed if and when any personal data might be processed. The principle researcher and investigator are obliged to give the participant the following details (part of the informed consent form – see section 6.6):

- Name and contact details (telephone number, email and address).
- Purpose of data collection.
- Procedural and processing steps revealing that they are legal, ethical and fair.

6.5.4 Data privacy Policy of MyCorridor system

MyCorridor system provides personalised and interconnected mobility services which will operate on existing infrastructure used by thousands or even millions of travellers. These services will be performed according to the following principles:

- All required user data will be stored at their profile and be securely protected by the relevant WP2 (Open Cloud System Architecture) mechanism. Relevant preferences relate to their transportation modes and everyday mobility and transfer preferences. The user will have the option to set or delete their profile. No personal information will be stored, all data will all be anonymised and aggregated and serve only analysis purposes;
- The user's location and route will be only temporarily stored (i.e. during a trip), in order to assist the user; they will be automatically deleted afterwards, unless the user wishes to store them;
- The user will have the capacity to view, change or delete- as he/she wishes- all stored data by the system (including their profile data, if chosen to be stored).

It should however be explicitly stated that the following data will either not be collected at all or, if voluntarily provided, it will be anonymised prior to being processed and will not be stored in any way that would enable an individual to be identified:

- Medical info.
- (real) Name, address, tel., fax, e-mail, photo, etc. of the user (any direct or indirect link to user ID).
- Any other preferences/actions by the users, except the ones that will be voluntarily provided for the purpose (in any case will not be connected to the user ID).

6.5.5 Coding Anonymised data and Storing

Information should be anonymised so that individual identities cannot be revealed. Anonymisation provides a safeguard against accidental or unauthorised release of personal and confidential information

in breach of any applicable legislation. There are different ways in which personal data can be modified to conceal identities:

- *Coded information* contains information which could readily identify people, but their identity is concealed by coding. The key to which is held by members of the research team using the information.
- *Anonymised data* with links to personal information is anonymised to the research team that holds it, but contains coded information which could be used to identify people. The key to the code might be held by the custodians of a larger research database.
- *Unlinked anonymised data* contains nothing that has reasonable potential to be used by anyone to identify individuals. Combinations of all demographic data that might lead to identification of individuals or small groups will be avoided (e.g. age, gender, nationality, occupational and Socio-Economic Status (SES), diagnosis, address, other contact details). In cases of in-depth qualitative data collection (e.g. ethnographic observations, interviews) with increased complexity of data collection, potential links in data identification will be judged on a case-by-case basis and it will be taken into serious consideration for ethics approval. . Appropriate steps will then be taken to comply with all applicable data protection legislation.

Any databases including participants' details will not be maintained after the end of the project, unless participants state so (i.e. in many occasions participants inform researchers that they would like to participate in other studies). In such cases, participants provide written informed consent of their willingness to share their personal details for these additional purposes. The latter also depends heavily on European laws, national laws and guidelines.

For the statistical analysis, the answers provided by the participants will be associated with their user group membership (if any) or age, gender etc. However, each month, and during the project, the anonymised data will be re-sorted randomly, to mix participants' order. Data handling will be carried out only for anonymised datasets and will be aggregated and consolidated by the partner who shall consolidate and analyse data.

Different templates will be prepared for data gathering based on data type. Additional testing materials related to data gathering will be used such as meta-data template (i.e. a template describing briefly the data types collected at each site and any related data that describe and present the procedure). Meta-data templates facilitate analysts to understand the procedures and the nature of tests conducted at each site. This proves very helpful and efficient in cases the analyst is not the person responsible for the test or is not a member of the test conduction team.

Separate common templates will be created for each instrument and technique applied. For example, interviews with open-ended questions will be transcribed under main topics for further content analysis and questionnaires could be available in electronic forms. Any such data collected will not contain personal information or where necessary, any personal information will be anonymised.

Participants will be informed about MyCorridor data privacy protection policy and relevant policies.

As databases are being developed and grow, confidentiality will become increasingly hard to maintain. Simple stripping of the participants name and its replacement with a code is no guarantee of complete confidentiality. The MyCorridor Ethics Board will especially scrutinise the security and privacy of information pre-processing within databases. Within MyCorridor the participant will be informed about the sharing of his/her data, even, if only anonymised data is being shared. There are solutions to the challenge of maintaining confidentiality including substituting numerical identifiers for names, aggregating data so that the performance of individuals is not obtainable, encryption or layering data.

6.6 Informed Consent

In general terms, informed consent is the process by which a participant will be fully informed about the research in which s/he is going to participate. It originates from the legal and ethical right that the participant has to direct what happens to his / her body and personal data and from the ethical duty of the investigator to involve the participant in the research. Seeking the consent of an individual to participate in research, reflects the right of an individual to self-determination and also his/her fundamental right to be free from (bodily) interference, whether physical or psychological, and to protect his / her personal data. These are ethical principles recognised by Law as legal rights. A distinction between three informed consent elements is possible:

- the information given;
- the capacity to understand it and
- the voluntariness of any decision taken.

The informed consent aims at ensuring that the user accepts participation and is informed about all relevant aspects of the research project; it should be given in written form after the candidate participants have been provided with clear and understandable information on their role (including rights and duties), the objectives of the research, the methodology used, the duration of the research, the possibility to withdraw at any time, confidentiality and safety issues, risks and benefits.

Nevertheless, researchers will obtain written (consent by participants prior any involving in user testing. An information sheet will accompany the consent form describing the main objectives of the project and of the evaluation to be carried out (see the detailed list in section 6.1). The informed consent forms will first be approved by MyCorridor Ethics Board prior distribution to potential participants. They will be sent (or handed out) to participants about one month before the actual session or the testing period instantiates. Participants will be informed about the project, test objectives and procedures prior receiving/ being handed the consent form. Pilot testing needs to be approved by the regional/ institutional Ethics committee(s) prior any testing takes place. The duration of pilot conduction, as defined in the Ethics application form should include the required/ planned periods for obtaining informed consent.

As previously mentioned, in the case of real-life travellers, the informed consent will be provided to them either through the respective service providers that will inform them about the integration and the use of their service in the context of MyCorridor one-stop-shop (unless this is not required by the existing Terms and Conditions they have already signed), through the MyCorridor vouchers or via the MyCorridor platform itself. The specific legal context has been defined in the session 6.7 in synergy with **A7.4: Operational, equity and legal issues including security and privacy**.

Some key principles are as follows:

- The participants will have sufficient time to read and understand the aims of the project and the pilots before they participate. They will be able to ask questions to the responsible person whose contact details are included in the consent form document. The consent form will be written in a way that by no means states or implies that the moral or legal rights of the person are affected or not respected (the informed consent templates based on the information to be included base on the WHO consent form templates).
- The information will be provided in simple language and be available in all pilot site languages as well (plus the English language). After the approval of the template, its translated consent form will be used with a small group of participants to validate that the included information and the chosen form of presentation is appropriate and understood by the participants.
- The procedure will be described in detail with all necessary steps to be taken or completed by the participants accompanied by an estimation of the duration of the session or the whole participation in the study. The participant by no means should feel any discomfort or inconvenience and they will not be harmed or be put in risk during the evaluation process. These are fundamental ethical aspects to be followed by researchers in any type of contact with participants.
- The participant should be informed about the study aims and benefits for the specific user group. If participants receive reimbursement or honoraria for their participation, then the amount/voucher. etc., should be relevant to the involved effort and by no means should be perceived as a mechanism of coercion or expectations to be fulfilled by all participants.
- The main investigator's /researcher's contact details will be included in the form in order that the participant will to be able to ask questions about the project and the study and receive answers.
- The participant should be aware at all times that their participation is on voluntary basis and they can withdraw from the study any time they wish without any consequences.

The form of informed consent is provided in Annex 4 of the current document. It should be noted that informed consent will be requested by both the travellers and the service providers that will participate in the MyCorridor pilots. The "Informed Consent" has been updated from the legal point of view with reference to the one reported in the D10.1 – POPD Requirement No.1, in order to make the form compliance with the EU General Data Protection Regulation (Regulation (EU) 2016/679) according to the section "The legal positions" reported below.

6.7 The legal positions

The MyCorridor project must comply with national and European data protection legislation, including the EU Data Protection Directive 95/46/EC (the "**Directive**") and, as of 25 May 2018, the EU General Data Protection Regulation (Regulation (EU) 2016/679) (the "**GDPR**"), which repeals the Directive. In this section, we refer to requirements in both the Directive (currently in force) and the GDPR. Personal data can only be processed if there is a 'lawful basis' to do so. Article 6 of the GDPR (and Article 7 of the Directive) set out the requirement to have either the consent of the individual or another lawful basis. It

is anticipated that the MyCorridor project will rely on consent as the lawful basis for processing personal data for the MyCorridor project pilots.

Under the Directive, valid consent means any *'freely given specific and informed indication of the data subject's wishes';* however, the data subject need only *'signify'* agreement. Article 6(1)(a) of the GDPR has a higher threshold than under the existing Directive for what is deemed adequate and valid consent, i.e., there must be a clear affirmative action from the individual. 'Consent' under the GDPR means "*any freely given, specific, informed and unambiguous indication of the data subject's wishes by which he or she, by a statement or by a clear affirmative action, signifies agreement to the processing of personal data relating to him or her.*"

The MyCorridor project will endeavour to meet the higher threshold of the GDPR from the outset, to avoid the need to seek fresh consent from individuals during the course of the MyCorridor project and thereby minimising disruption to the project and to individual participants.

Additionally, under the GDPR:

- requests for consent must be clearly distinguishable from other matters and consent must be in an intelligible and accessible form, using clear and plain language (Article 7(2) GDPR). This would seem to rule out general acceptance (in practice this means that once MyCorridor has obtained personal information from an individual it will only use that individual's details for the purpose explained to that individual at the time the consent was given);
- data subjects must be able to withdraw consent as easily as it was given and must be told upfront that this is possible (Article 7(3) GDPR); and
- data controllers must keep clear evidence of consent (Article 7(1) GDPR).

The MyCorridor consent form

In order to satisfy the requirements for valid consent under the Directive and the GDPR, as mentioned above, travellers participating in the MyCorridor project pilots will be invited to agree or disagree to MyCorridor processing their personal information for the purposes of the MyCorridor project pilots, by completing a copy of the form at Annex 4, prior to MyCorridor processing their personal information. Through completing this form, an individual will be providing consent to their personal information being processed for the purposes of the MyCorridor project pilots by way of a clear affirmative action, satisfying the higher threshold of consent required under the GDPR.

For other MyCorridor pilots or projects involving 'real-life' travellers and third party service providers, where the consent form at Annex 4.1 is not used, the Consortium shall ensure that appropriate GDPR compliant measures are put in place for obtaining individuals' consent, prior to collecting or processing personal information relating to those individuals.

Sensitive personal data / special categories of personal data

Under Article 8 of the existing Directive and under Article 9 of the GDPR more stringent consent is required to process sensitive/special personal data (e.g. information relating to physical or mental health). The requirements from a practical perspective are largely similar under the Directive and the

GDPR. Under the GDPR, *'explicit'* consent is required for processing *'special categories of personal data*'. The GDPR does not define *'explicit'* consent; however, the Article 29 Working Party refers to explicit consent as encompassing "*all situations where individuals are presented with a proposal to agree or disagree to a particular use or disclosure of their personal information and they respond actively to the question, orally or in writing".* Whilst we do not anticipate the need to, nor do we have any intention of, processing personal sensitive personal data, should this change in the future, we shall ensure that we request prior explicit consent from the individual in accordance with the above.

Information received from an intermediary

Under the GDPR, both the processor and the controller will share liability for the processing of personal data; therefore it is important that compliance with data protection laws can be easily and clearly evidenced. Ideally this will be contained in the MoUs.

OC will reviews any Memorandums of Understanding ("MoU") with the entities and each intermediary's terms and conditions, to check it appropriately covers any sharing of personal data. Affirmative consent will likely be obtained from the intermediary, which will include consent to share the data with the relevant entities within the consortium for informed purposes.

Open access

As part of the MyCorridor project, MyCorridor will be providing open access to the scientific results from the project pilots. Where necessary any personal information will be anonymised and at the point of publication / point of sharing any information relating to the MyCorridor project with any third parties, any such information shared will not contain any personal data for the purposes of data protection legislation.

Anonymisation/pseudonymisation

The GDPR recommends anonymising and pseudonymising personal data. Details of how we process and protect individuals' data will be set out and regularly updated in the data management plan ("**DMP**").

Privacy and Cookies policy

The European E-Privacy Directive (Directive 2002/58/EC) complements data protection legislation and applies specifically to privacy of electronic communications. It is relevant to the MyCorridor project in relation to the downloading and use of cookies on the MyCorridor platform and also to the extent that MyCorridor intends to carry out direct marketing to individuals via email, phone, and SMS.

Cookies

In compliance with the data protection legislation and the E-Privacy Directive, MyCorridor will have a cookies policy, accessible via the MyCorridor website, clearly explaining to users what the cookies do; the potential consequences of allowing the cookies; and why MyCorridor is using them. MyCorridor will also obtain informed consent from users prior to using these cookies.

Privacy

MyCorridor's privacy policy will also be accessible via the MyCorridor website and in accordance with the GDPR, it will provide detailed information relating to (among other things) the transfer of data between relevant parties within the MyCorridor consortium and will clearly explain to users MyCorridor's policy and practices regarding MyCorridor's collection, use and disclosure of users' personal information.

6.8 Incidental Findings

They are defined as the findings that maybe by-products or outcomes of the study that were not part of the main research questions and objectives but could be of importance for the physiological, psychological and metal wellbeing of the participant. The number and type of incidental findings could be different for each site and valuable for both the person and the other stakeholder groups.

Any findings that are related to participant's health during the tests will be communicated in writing to the test participant only, supporting them to contact medical support if needed. Such incidental medical findings, will not be communicated to 3rd parties (including insurances, authorities, etc.).

6.9 Security and Identity Management

The security Information Technologies (IT) system should ensure that all personal data against any potential threats of unauthorised access or disclosure risks as defined by the OECD – Digital Security Risk Management. Any security related threats or issues should be handled on a network area level and a cloud-based level. Security is an integral part of IT and, especially in MyCorridor, the most advanced security measures and protocols will be applied, that will be implemented as security modules built in the cloud-based infrastructure of choice, providing all the required security modules and features to ensure undisrupted service provision. Therefore, security data transmission, transferring, sharing, whilst protecting the identity of the person the data belongs to and simultaneously maintaining and managing a system of high confidentiality, integrity, quality and efficiency, is of core importance for safeguarding the security and identity protection principles. Limiting access to certain personnel enhances security and data integrity. Data should be accessed and modified only by authorised personnel (in most cases by the principal site investigator). Although most information and data will be stored on cloud service(s), consideration should be made about the security and threats of computers and applications used to access these data. Encrypting data before data are stored on the cloud servers in envisaged, especially in case of data hack. Information flow should be monitored and controlled to be able to control for security bridges and rectify in case of security breach. In addition, data should be stored in a secure area with increased security protocols and firewall protection. Data should be regularly checked for quality (e.g. corruptions because system failures, crashes, malicious acts, accidental losses or alterations) either with automated tools or manually by the administrator. Data privacy, availability and auditing should be ensured in a way that will not affect the system's performance. In other words, any applied protocols should be flexible and viable for the system and its users. By system we mean the final cloud-based MyCorridor one-stop-shop with all integrated modules. Making the MyCorridor system secure entails the following technical security requirements.

- Physical integrity: the system is protected by physical failures (e.g. power).

- Logical integrity: robust databases where erroneous or required modifications do not alter the structure and connections of fields.
- Element integrity: accuracy of added data.
- Control of access: levels of authorised entry to the system based on access levels (e.g. the principal investigator may have access to personal data and a data analyst will have only access to the database with anonymised and not-identifiable-data).
- User authentication: related to the access control (just above) and access is given with registered credentials provided (and sometimes controlled) by the administrator. Permission is granted to certain registered users. The cross-border aspects in specific have to be the focus of MyCorridor. The generic models for domestic and cross-border electronic authentication of the pilot site countries will be sought. In order to achieve compatibility between the two systems to the point where a user of the first system may receive services from the second system, adapter components will be introduced into the systems (cross border and token adapters).
- System availability: uninterrupted data flow for authorised users whenever a request is sent.
- Auditability: record activity and access details (who, when, which data, duration of session, and data transferring (if any)).
- Application of security policies and standards: setting the requirements for document encryption, use of digital signatures, setting security protocols (like SAP) to ensure secure communication channels, use personal anti-virus software and personal firewalls and encryption mechanisms for data storage and communication (e.g. sending via email protocols).

All security issues will be dealt within A2.3: Interoperability and cross-border security issues in the project. MyCorridor key challenges lie in interoperability and cross-border security of the MaaS interconnected services, as follows:

- Different user credentials that link the user's identity with a token, reliability of each credential, token security levels, tokens issued by different operators, etc.
- Different technical infrastructure and equipment in use.
- Different authentication protocols and procedures.
- Different sets of personal data.
- Acceptance and trust of personal data from one country to another.

Special attention will be given to security issues regarding cross-border identification. ISO 27000 series standards will be followed along with ISO/IEC 13335, BSI 100-1 to BSI 100-2 for personal and application data.

6.10 Risk Assessment and Management

The Risk Assessment and Management analysis performed in the previous phase of the project and reported in the D10.1 (POPD Requirement No.1) has been revised by the pilot project leaders and largely confirmed.

It is not possible to conceive a procedure, investigation, or process which would be without any risk. One of the most important factors in the assessment of risk is the perception of the prospective participant of the importance of risk. The participant's life situation may substantially influence the way in which a risk is perceived. The end point of the process is the consent given by the person to be part of the research project, having considered all aspects of the process and asked all relevant questions. All relevant information – is given to the participants. This means that the purpose and objectives of the project MyCorridor will be carefully explained and will be prepared prior any testing takes place. Users will decide to participate and consent will be obtained without coercion or undue pressure being applied.

MyCorridor declares that:

- There will be no risk of physical damage during the MyCorridor pilots. MyCorridor is web/mobile based system and the terminals used will be the current participants' terminals (i.e. mobile phones, etc.). There will be no extra equipment or mobile devices used by the participant. But, if any extra equipment is needed, it will be evaluated for personal safety. These tests will be performed for complete configuration and not only for individual equipment as an essential part of technical validation and verification plan necessary to be conducted before using any tools or services with real users.
- Psychological consequences will be carefully examined.
- Social inconveniences will be minimised (no additional stress for users, cost reimbursement for additional transport costs, etc.).

Table 2: Preliminary considerations regarding Ethical Risk Management in MyCorridor.

Ethical and Social risks	Description	Ethical Risk Management in MyCorridor
Ethical and legal framework applied	All relevant legislation, regulation and ethical codes should be taken into account; it has to be defined in detail how these provisions will be met in terms of processes, timing and responsibilities.	These questions have to be raised during the planning phase, otherwise in case a problem arises, it will be hard to remedy and it may even have legal consequences. The project has included these considerations in session 5 (Summary of MyCorridor Questionnaire on Ethics and legal issues) of the current document and, if relevant, also in its annual reporting. Both local ethical bodies and a project-level Ethics Management Panel will oversee the ethical concerns involved in the project.

Ethical and Social risks	Description	Ethical Risk Management in MyCorridor
Transparency and consent of the end-user	The informed consent aims at ensuring that the user accepts participation and is informed about all relevant aspects of the research project; it should be given in written form after the users have been provided with clear and understandable information about their role (including rights and duties), the objectives of the research, the methodology used, the duration of the research, the possibility to withdraw at any time, confidentiality and safety issues, risks and benefits.	The "Informed Consent" includes the following elements: • Project description • Scope of the Pilot • What type of information is needed to be collected • What type of information is needed to be shared to third party • Description of the involvement of the participation in the Pilot • The value that a participant bring to the MyCorridor project • What it will be happened to any provided information and how it will be stored • How long the Pilot will last • Contact person • What it will be happened to the results of the Pilot • Description of the possible benefits of taking part in the Pilot • Description of any risks • MyCorridor's Privacy Policy
Privacy and data protection	Anonymised data will be processed at each pilot site. Any personal data that is provided by an individual to a pilot site will be anonymised prior to any further processing and prior to any data being shared with other entities within the consortium. At each pilot site the name will not be connected to other characteristics (e.g. age, gender, nationality). Participants will participate only if they provide informed consent. We will ensure that all handling and processing of personal data is carried out in accordance with all applicable data protection laws. Each pilot site shall be individually responsible for ensuring that its collection and handling of personal data is carried out in accordance with its jurisdiction's personal data laws and regulations. We do not and will not knowingly collect information from any unsupervised child [under the age of 13],	Data privacy policy is elaborated in D2.1: Data management plan (DMP) with explicit consideration for the following: • What kind of data will be processed? • What is the purpose of the processing? • Will the data exceed the purpose of the study? • Are there procedures ensuring that data is processed only for the originally identified purposes? • Who is the owner of the data? • Are data connected to other information? • Will data be commercially exploited? • What is the duration of the storage of the data?

Ethical and Social risks	Description	Ethical Risk Management in MyCorridor
	unless their parent or guardian has provided us with their consent. As European States may interpret the scope of these instruments quite differently, special attention should be given to national legislation. Moreover, countries may adopt even different views on what the legal term "personal data" refers to, either leaving outside the scope of relevant legislation only anonymised data or adopting an interpretation based on whether the person is identifiable by the controller of the data. These provisions have to be respected even if the users have given their consent for the processing of their personal data. Especially regarding sensitive data, like physical or mental health, sexual orientation and ethnic origin, more restrictions apply. However, at this stage, we do not anticipate the need to collect any sensitive personal data. Should this requirement change, each pilot site shall ensure that it has adequate procedures in place to obtain the necessary explicit consent and to protect this sensitive personal data in accordance with all applicable legislation and regulation. The MyCorridor consortium and each pilot site shall comply with their obligations to mitigate potential risks arising related to the processing of personal data, such as identity theft. Personal data will also only be stored for as long as is necessary to fulfil the purpose for which the personal data was collected. All individuals sharing personal information with a pilot site will be informed of their rights in relation to that personal data.	• Where will the data be stored and according to which national legislation? • Who will access the data? Are they secured? • Will the user be recorded? • Will biometrics be implemented? • Who will supervise the data protection? The DMP is a live document, regularly updated, to track how all data collected in relation to the MyCorridor project is handled and processed in compliance with all applicable data protection legislation and regulations. This DMP is supported by a Data Privacy Impact Assessment (DPIA), which will be completed as soon as practicable prior to collecting any personal data and at various phases throughout the life of the MyCorridor project. The DPIA will be completed in accordance with the General Data Protection Regulation (Regulation (EU) 2016/679). The DPIA will serve as a useful tool for monitoring and mitigating risk related to the handling of individual's personal data. Data can be used only for the initial purpose for which they were collected and, in relation to personal information, within the remit of the relevant informed consent. Anonymisation or pseudonymisation will be used where appropriate to prevent violations of privacy and data protection rules. Processing has to be limited to what is truly necessary and only for the period that is necessary. Where possible, less intrusive means

Ethical and Social risks	Description	Ethical Risk Management in MyCorridor
	Further information on how we handle personal information will be elaborated also in the D7.3 (B2B master contract, B2C terms of use, privacy and cookie policy).	for realising the same end have to be considered.
Ethical duties beyond the research lifetime – Exit strategies	How the knowledge produced will be used, whether users will benefit from it and what will happen to users after the end of the research is also to be considered. This is particularly relevant for research which runs for a long time and has an impact on travellers' everyday routines. For instance, people participating in pilot testing who have been using technological assistance while commuting, they would need to adapt to the lack of technology at the end of the research process.	Measures will be taken so that users fully understand that the project applications may be withdrawn after the end of the project or be offered under commercial terms and that a deterioration of the status (e.g. financial, social) of the user will not occur as a result of the end of the research. To address this challenge, exit strategies in the concluding phase of the project have to be foreseen, encompassing plans for maintaining solutions and ensuring their take-up.
Safety	Pilot testing should not entail any undue risk for participants.	Guidelines for user involvement will be provided in D6.1: "Pilot plans framework and tools" for M12 and use of technologies will be supervised; though, as mentioned in this Deliverable, no actual risks have been recognised so far.
Users' engagement	Research has to be inclusive and representative of various user groups. The selection and recruitment of users is a crucial part of the user involvement process, as it will impact the quality of the outcomes and the sustainability of the research or policymaking process. At this stage a satisfactory number and combination of user characteristics is sought; gender balance and equality should be addressed.	MyCorridor will target users in the large sense: citizens who are travellers and commuters using private and public transport modes. The substantial number of users will ensure a wide trial perspective, including: i) different countries, ii) different age groups, iii) various types of travellers and commuters, iv) various social backgrounds, v) different living and travelling arrangements and patterns, and vi) gender balance. As previously mentioned, the vast majority of the pilot population for MyCorridor will be

Ethical and Social risks	Description	Ethical Risk Management in MyCorridor
		real-life travellers. Especially for this case, the way the users will be engaged and provide their consent will be objective of **A7.4: Operational, equity and legal issues** including security and privacy and have also been detailed in the current document. But, in general, all different mechanisms to be applied for the user recruitment and engagement will be defined in D6.1: "Pilot plans framework and tools" for M12. The annual project reporting will be the occasion to evaluate the user involvement process and mitigation strategies to be implemented with regards to level of technology maturity and availability and applicability of the evaluation framework and plans.

Ethics related risks will be systemically scrutinised and mitigation strategies will be proposed per each in the context of the horizontal risk assessment that will be held in the project and will address all types of risks. This will take place in WP2, and specifically A2.4: "Risk Assessment" and will be finally reported in D2.3: Risk analysis (M30, R, CO). The project Risk Analysis will use an extended Failure Mode Effects Analysis (FMEA) methodology and will address all types of risks, namely: technical, behavioural (i.e. users not able to correctly operate the services due to UI or misconception of the services), legal and business-related risks. The identified risks will be calculated and rated in terms of occurrence probability, severity, detectability and recoverability, and for the most critical of them mitigation strategies will be proposed. This will be performed a priori towards the beginning of the project (by Month 12), to predict potential risks and alleviate them as well as a posteriori, during the project pilots, to evaluate and revise the risk compensation strategies towards commercialisation and exploitation. Risks and opportunities of emerging new technologies, platforms and standards will be also constantly assessed.

6.11 Incentive Schemes

There are 2 types of incentive mechanisms that will be applied in MyCorridor, addressing the 2 main categories of participants in MyCorridor pilots, namely those users that will be specifically recruited by MyCorridor for performing specific test scenarios and those that will not be recruited by MyCorridor but will be real-life travellers:

- **Incentives for real-life travellers, not specifically recruited by MyCorridor**: Real-life travellers will be incentivised to use the services provided through the MyCorridor one-stop-shop through discounts that will be offered to them by the respective operators. This discount has been anticipated to be covered by the project in the sense of "compensation for evaluation activities' and has been allocated in the different pilot leaders of the corridor.
- **Incentives for participants specifically recruited by MyCorridor**: As previously mentioned, there will be two (2) key clusters of pilot participants across the 2 pilot rounds of MyCorridor; namely service providers/developers and travellers. Both groups of participants will receive an incentive as compensation for their participation. It will not be conditional based on performance or restricted to finalization of the actual test. In general, it is not envisaged to give money to the pilot participants. Anyway, before performing pilots, the reimbursement mechanisms will be revisited by MyCorridor Ethical Boards and approved.

Each pilot site will define the incentives appropriate for the participants to be recruited according to the thresholds imposed by their national and institutional regulations. A large number of participants is considered for the MyCorridor pilots and ensuring participation and attendance at follow-up sessions is – in some occasions – critical for not only the success but the everyday running of pilots. It is a fine line between creating a culture of incentives when recruiting people and the MyCorridor Ethics Board will oversee and approve (or not) the incentive schemes chosen by each pilot site, apart from the research protocol approval by the local Ethics committee. Therefore, based on the evaluation plans appropriate incentives will be chosen. As commitment is essential for the success of the project, users will receive some form of reimbursement. In case of recruiting employees, incentives are not used as people are already paid for their time.

Participants should be informed of the presence/absence of incentives when recruited and a statement needs to be added in the consent form. In case of legal restrictions or policies, the ethics responsible at each pilot site should inform the Ethics Board. An alternative to cash is using vouchers; sometimes it is easier for evaluation moderators to carry/use and they should be representative of the demographics (i.e. have an added value for older citizens).

It is upon the discretion of each partner to decide the incentive scheme to use (if not to use). Other options include sharing the results of the study, making charitable donations, creating a prize draw and offer non-monetary gifts.

A specific session will be devoted in D6.1: "Pilot plans framework and plans" regarding the recruitment and engagement of the end-users that will participate.

6.12 European Charters, Declaration and Conventions

According to Art 19: Ethical Principles the following encompasses the legal foundation for MyCorridor:

> *"All the research and innovation activities carried out under Horizon 2020 shall comply with ethical principles and relevant national, Union and international legislation, including the Charter of Fundamental Rights of the European Union and the European Convention on Human Rights and its Supplementary Protocols."*
>
> http://ec.europa.eu/research/participants/data/ref/h2020/legal_basis/fp/h2020-eu-establact_en.pdf

Any arising ethics related issues are handled following the following principles:

- Helsinki Declaration of 1964 (revised version 2004).
- European Convention of Human Rights.
- Rules of the Convention of the Council of Europe for the protection of individuals (automatic processing of personal data).
- European Directive 95/46/EC as repealed and replaced by the General Data Protection Regulation (Regulation (EU) 2016/679), for the protection of personal data.
- Charter of fundamental human rights (Art. 8, 2000) about the personal right of each person to protect and access their personal data. Such data can be processed only after the person has given their consent and any related processes can be controlled by an independent authority.

Specific Laws and Directives to be considered per area are summarised in the table below.

Table 3: Legislation and non-binding instruments to be considered by MyCorridor's Ethics Board.

Ethical & social issue	Ethical field	Law/directive
Human Dignity and integrity of user	Human rights	• Universal Declaration of Human Rights (United Nations) • Convention for the Protection of Human Rights and Fundamental Freedoms (Council of Europe) • European Charter of Fundamental Rights • Draft recommendation of the Council of Europe on the promotion of the human rights of older persons • European Charter of the Rights of Older People in need of Long-term care and assistance
Privacy	Data protection	• Directive 95/46/EC as repealed and replaced by the General Data Protection Regulation (Regulation (EU) 2016/679) of the European parliament and the Council (1995) on the protection of individuals with regard to the processing of personal data and on the free movement of such data. • Directive 2006/24/EC of the European Parliament and of the Council of 15 March 2006 on the retention of data generated or

Ethical & social issue	Ethical field	Law/directive
		processed in connection with the provision of publicly available electronic communications services or of public communications networks and amending Directive 2002/58/EC. • Directive 2002/58/EC of the European Parliament and of the Council, concerning the processing of personal data and the protection of privacy in the electronic communications sector. • Will take into account developments of Reform of the legislative framework for personal data protection (In January 2012, the European Commission proposed a reform of the Directive 95/46/CE, which constituted until now the basic instrument for personal data protection, in the form of a global Regulation on data protection 2012/001 (COD), supplemented by Directive 2012/0010 (COD) concerning the processing of personal in the area of police and judicial cooperation in criminal matters.) • Art.29 Data Protection Working party: Working Document on Privacy on the Internet.
New Technologies	Liability and Safety	• Directive 85/374/EEC on liability for defective products as amended by Directive. • 1999/34/EC, hereinafter "the defective products Directive" • Directive 2011/24/EU on the application of patients' rights in cross-border healthcare. • Directive 90/385/EEC on active implantable medical devices and Directive 93/42/EEC on medical devices and Directive 98/79/EC on in vitro diagnostic medical devices. • Directive 98/34/EC of the European Parliament and of the Council of 20 July 1998 amended by Directive 98/34/EC laying down a procedure for the provision of information in the field of technical standards and regulations and of rules on information society services.
Disability	Accessibility	• Disability Rights Commission: Guidelines for Ethical research (2004). • UN Convention on the Rights of Persons with Disabilities. • Commission's proposal for a Directive on the accessibility of public sector bodies' websites. • Accessibility Act.

As mentioned already, in addition to the above legislation, the MyCorridor Questionnaire on ethics and legal issues (Annex 1) has been used to collect national guidelines and legislation based on previous project experiences. Those are summarised in section 5 of this document.

7 Communication with participants

Communication with participants should abide with fundamental human rights principles. Participants should not feel coerced, threatened, stressed (resulting from investigator's behaviour).

Deception

Researchers do not deceive by any means prospective participants about research that is reasonably expected to cause physical pain or severe emotional distress. Researchers explain any deception that is an integral feature of the design and conduct of an experiment to participants as early as feasible, preferably at the conclusion of their participation, but no later than at the conclusion of the data collection, and permit participants to withdraw their data. No deception will take place within MyCorridor pilots and the user will be informed at all evaluation stages about the objectives and the procedures related to the pilots and how their data will be handled, processed, and stored.

Debriefing

Researchers provide a prompt opportunity for participants to obtain appropriate information about the nature, results and conclusions of the research, and they take reasonable steps to correct any misconceptions that participants may have of which the researchers are aware. Researchers also inform the participants about symptoms or diagnoses of diseases that have been discovered during the observation; especially if the symptoms have not discovered yet by a physician. Relevant test results will be provided to participants General Practitioner. The debriefing has to be documented and will be signed by both sides. Summaries and copies of research reports will be given to research participants in appropriate accessible formats (e.g. larger font size, use of simple text accompanied by photographs, oral communication, etc.).

8 Conclusion

The current document constitutes an update of the first version of the MyCorridor Ethics Manual, namely D10.1: "POPD – Requirement No.1". Ethical issues will be discussed in annual reports and Pilots plans deliverables.

MyCorridor ethics policy acts as a reference document to govern all activities in the project; from research and development activities, pilot activities to data analysis and reporting. This document is a "living" document to be updated with any arising issues or topics not originally anticipated during these early stages of the project.

Major ethical issues were addressed and listed in this document with consideration and reference to international, European and national legislation and guidelines, but also with respect to the national and local7institutional regulations when applicable. The ethics management team (MyCorridor Ethics Board) will oversee and scrutinise the research protocols with regards to privacy, confidentiality, anonymity and risk assessment and mitigation.

Obtaining consent is of core importance in testing and ethics. The informed consent is a very important part of the research process; that is why a lot of space in the present manual is dedicated to this issue. The relevant facings of a valid informed consent for MyCorridor are described. Since not all investigators might be familiar with compiling and the documentation of informed consent, such information is added (section 6.6 and Annex 4). No experiments are being performed with persons unable to give a valid consent. The MyCorridor user groups do not include mentally disabled people.

Data privacy protection is a very important aspect in MyCorridor. The key principles of data privacy are presented in this document and are addressed in detail for all activities of the project in the data management plan deliverable (D2.1). No experiments with human beings will be conducted in MyCorridor, whereas the personal data will be strictly protected and unlinked anonymised. No genetic information will be collected. No user personal data and preferences will be centrally stored, nor sent around in the Network, nor will be available to any third party (i.e. for advertisement, marketing or even research – outside MyCorridor objectives).

All private information is held confidential.

With reference to the deliverable D10.1, the following activities have been carried out:

- The Ethics Board synthesis has been revisited and the re-appointment of nominated persons has been realised. The external expert that will be consulting MyCorridor Ethics Board has been also defined and engaged.
- The detailed data privacy policy – across all phases of the project; user needs, development, pilots – has been tackled in WP2: Open Cloud System Architecture and reported in D2.1: Data management plan.
- The MyCorridor Questionnaire on ethics and legal issues (Annex 1) has been revisited in collaboration with A7.4: "Operational, equity and legal issues including security and privacy" and has been used to collect national guidelines and legislation based on previous

project experiences. The revisited form and the aggregated responses from test sites on local regulations, legislation and practices have been included in D9.2. (see chapter 5 and Annex 1)

- The Ethics Controlling Report has been developed. Through that, the test sites will report the level of compliance to the Ethics Code of Conduct of Research. The form has been included in the current document (see Annex 2).
- The legal context of incentives, the Informed Consent form (and any adaptations that may arise), the way that will be provided and signed by all types of participants, the ethical risk assessment first complete round and the overall Ethics Policy of the project has been revised and confirmed.
- The Risk Assessment and management analysis has been revised and confirmed.

Next steps in ethics related work in MyCorridor are as follows:

- The results of the Ethics Controlling Report will be respectively reported in annual reports and Pilot Plans Deliverables (D6.1 & D6.2).
- Any required or requested authorisations and approvals remain official project documents at any times and they will be annexed in D6.1: "Pilot plans framework and tools".
- Detailed guidelines for user recruitment, involvement and engagement in abidance with the Ethics Policy will be provided in D6.1: "Pilot plans framework and tools" for M12.
- The data information sheet that will accompany the Informed Consent form will be provided in D6.2 (as the specific test context is a prerequisite).
- Update version of the Data management plan (D2.1) will be elaborated.

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Annex 1: MyCorridor Questionnaire on Ethics and Legal Issues

Introduction

This is a template on ethical and legal issues that has to be completed by all partners who conduct pilots entities, both before the pilots take place and after to check compliance. The questions and the documents of the different sections are related to the current document (D9.2. MyCorridor Ethics Manual), in which background information concerning the different questions and subsections is provided in more detail. Within the MyCorridor Ethics Manual the content of the template has been justified on its scientific and legal basis.

Questionnaire on ethical and legal issues: This questionnaire on ethical and legal issues has to be filled in by the responsible investigator conducting the trials involving human participants. It aims to serve as a checklist reminding the researcher to take into account all relevant ethical aspects before planning and later on conducting any experiment within MyCorridor. The questionnaire itself is divided into different subsections (e.g. informed consent, ethical control instruments, privacy, safety, risk assessment, etc.).

Questionnaire on Ethical and Legal issues

Should all testing related activities be approved by a local research ethics committee?

❑Yes ❑ No

A) Participants and informed consent

1. **Do you intend to conduct pilots that will require the obtainment of participants' consent?**

   ❑Yes ❑ No

   If ***yes***, briefly explain which specific aspects of the trials you will need to obtain informed consent for:

   _____

2. **Do you intend to conduct pilots with individuals that might not understand the informed consent form?**

   ❑Yes ❑ No

   If ***yes***, briefly explain the procedures you follow in order to obtain informed consent:

   _____

3. **Is the oral consent of a participant in presence of a witness appropriate in accordance with your national legislation?**

   ❑Yes ❑ No

4. **Is there an international or national legislation, which you must follow when performing tests within the MyCorridor project**

   a) involving healthy human participants?

   ❑Yes ❑ No

   If ***Yes***, please give details (reference number and short description of procedure):

b) involving participants with cognitive impairments / learning difficulties?

❑Yes ❑ No

If ***Yes***, please give details (reference number and short description of procedure):

c) involving *illiterate* or *with co-morbid conditions* participants?

❑Yes ❑ No

If ***Yes***, please give details (reference number and short description of procedure):

B) Ethical control instruments

5. At which level of your organization / enterprise, *ethical controls* are audited?

❑ laboratory or workgroup

❑ division or department

❑ institution

❑ regional

❑ national

6. Is there an ethics controlling body in your region / country?

❑Yes ❑ No

If ***Yes***, please give details about the body relevant for you and the procedure that has to be adhered to in order to obtain ethical approval of experiments:

7. Is there a local ethics controlling committee, that your organisation is obliged to get approval from, for the experimental procedures before beginning with the experiment?

❑Yes ❑ No

If ***Yes***, please give details of the relevant body and shortly describe the specific procedure:

8. **Is there an established ethical control procedure which you must follow before performing tests with**
   a) healthy human participants?

   ❑Yes ❑ No

   If ***Yes***, please give a brief description.

b) human participants with cognitive impairments / learning difficulties?

   ❑Yes ❑ No

   If ***Yes***, please give a brief description.

c) *illiterate* or *with co-morbid conditions* participants?

   ❑Yes ❑ No

   If ***Yes***, please give a brief description.

C) Privacy

9. **Is personal data belonging to individual participants recorded as part of the trial?**

   ❑Yes ❑ No

10. **If so, do you plan to collect also sensible personal data (e.g. health-related information)?**

   ❑Yes ❑ No

11. **Is there an established Data Protection Authority issuing procedures / standards you must follow before performing tests with human participants and their personal / private data?**

   ❑Yes ❑ No

   If ***Yes***, please give a brief outline of it:

   If ***No***, please explain briefly what corrective actions you will take to ensure privacy of personal data of participants:

12. Do you follow written procedures for protecting privacy?

❑Yes ❑ No

If ***Yes***, please give a brief outline of it:

If ***No***, please explain the reasons briefly and submit any corrective actions you will take for OC review:

13. Do you follow or are you aware of any official national or international guidelines on protecting privacy?

❑Yes ❑ No

If ***Yes***, please give a brief outline and provide references:

If ***No***, please contact OC.

14. Do you identify persons and their professions who are authorised to have access to the data collected and / or who have access to any data storage devices, both paper-based and electronically?

❑Yes ❑ No

If ***Yes***, please give a brief outline and provide references.

D) Safety

15. Will you provide information to the participants if you become aware of an illness that could create risks to other participants?

❑Yes ❑ No

If ***Yes***, please give a brief outline of it and provide some references:

16. Is every pilot implementation evaluated for possible side-effects?

❑Yes ❑ No

If ***Yes***, please give a brief outline of it:

17. Do have written procedures for safety for employees and volunteers within your own group or institution?

❑Yes ❑ No

If ***Yes***, please give a brief outline of it:

If ***No***, please explain the reasons briefly or what corrective actions you take:

E) Risk assessment

18. Do you have procedures to perform risk-assessment concerning breach of privacy and / or breach of safety?

Yes No

If ***Yes***, please give a brief outline of it:

If ***No***, please explain the reasons briefly and refer any corrective actions you will take to OC:

19. Is your organisation insured against risks as a result of breach of privacy and safety?

Yes No

If ***Yes***, please give a brief outline of it and state the insurer, if possible:

If ***No***, please explain the reasons briefly and state who would cover any insurance-related costs:

20. For conducting research and manage the risk, do you need to involve other organisations (unit, division, department etc.) that might have influence on your research activities as well as on your ethical and legal conduct?

Yes No

If Yes, please give a brief outline of it:

Annex 2: MyCorridor Ethics Controlling Form

Introduction

This is a template ethics controlling form, defined within the MyCorridor Ethics Manual, which has to be completed by all partners who conduct pilots, both before the pilots take place and after to check compliance. The questions and the documents of the different sections are related to the current document (MyCorridor Ethics Manual, D9.2), in which background information concerning the different questions and subsections is provided in more detail.

Ethics controlling form: This form has to be filled in by the responsible investigator conducting the trials involving human participants. It aims to serve as a checklist reminding the researcher to take into account all relevant ethical aspects before conducting any experiment within MyCorridor. The questionnaire itself is divided into different subsections (e.g. informed consent, ethical control instruments, privacy, safety, risk assessment, etc.).

Ethics Controlling Form

Have all testing related activities been approved by the local research ethics committee (if applicable)?

❑Yes ❑ No

A) Participants and informed consent

1. **Have you obtained participants' consent (if applicable)?**

   ❑Yes ❑ No

   If ***yes***, briefly explain which specific aspects of the trials you have obtained informed consent for: _____

2. **Will you conduct pilots with individuals that might not understand the informed consent form?**

   ❑Yes ❑ No

   If ***yes***, briefly explain the procedures you have followed in order to obtain informed consent: _____

3. **Is there any doubt about the individuals' capacity to consent?**

   ❑Yes ❑ No

   If ***Yes***, please clarify, for each case, who has provided consent in such instance: _____

4. **a) Has the wording which seeks to gather individuals' informed consent been provided in common language to be understood by "the man/woman in the street"?**

   ❑Yes ❑ No

   If ***no***, why not? Please provide an example of any *technical or confusing terms* used within the description.

   b) Has the participant been given sufficient time to reflect upon his/her decision regarding their giving or withholding consent?

   ❑Yes ❑ No

   If ***no***, why not? Please indicate, for each case, the time given to the participant and the reason of such limited time.

5. **Is the participant unable to provide consent for any reason?**

❑Yes ❑ No

If ***yes,*** **no experiment will be performed since these participants are excluded from MyCorridor trials. Please list here each excluded case.**

6. **Does the participant object in either words or body language or any physical action that can be interpreted to that end?**

❑Yes ❑ No

If *yes* (he/she does object) no experiment will be performed since these participants are excluded from MyCorridor trials.

7. **Is the participant, for any reason, unable to read the form by him-/herself?**

❑Yes ❑ No

If ***yes***,

There are a range of people who may be unable to read the consent form; these include those who have severe visual impairments (e.g. cataract, glaucoma). Please see question 9.

8. **Is the participant unable to read the consent wording?**

❑Yes ❑ No

If ***no***, please continue with the question 10.

If ***yes***, be advised that any participant that is not able to read must give oral consent which has to be witnessed at least by one person. If that is the case, please ensure that you record the name of the witness when recording the individual's grant of consent.

Please see question 9.

9. **Is the oral consent of a participant in the presence of a witness appropriate in accordance with your national legislation?**

10. **If there is an international or national legislation which you must follow when performing tests within the MyCorridor project, please explain how you have assured compliance:**

B) Ethical control instruments

11. If there is a <u>local</u> ethics controlling committee that your organisation is obliged to get approval from for the experimental procedures before beginning with the experiment, have you obtained this approval?

❑Yes ❑ No

If ***No***, please explain why and shortly describe how you plan to solve this issue:

12. If there is an established ethical control procedure which you must follow before performing tests, please explain how you have assured compliance:

C) Privacy

13. What personal data belonging to individual participants will be recorded as part of the trial? Please list them here:

14. If there is an established Data Protection Authority issuing procedures / standards you must follow before performing tests with human participants and their personal / private data, please explain here how you have assure compliance:

15. If you follow written procedures for protecting privacy, please state the procedure you put in place to comply with these procedures during the MyCorridor pilots:

16. If you follow any official guidelines on protecting privacy, please explain here the procedure you put in place to comply with these procedures during the MyCorridor pilots:

17. Have you clarified to the participants that all data collected in the activities they are participating in will be kept entirely confidential and that their anonymity will be protected in full?

❑Yes ❑ No

If ***Yes***, please give a brief outline and provide references:

18. Have you identified persons authorised to have access to the data collected and / or to any data storage devices, both paper-based and electronically?

❑Yes ❑ No

If ***Yes***, please give a brief outline and provide references.

D) Safety

19. Have you provided information to the participants about any participant's illness?

❑Yes ❑ No

If ***Yes***, please give a brief outline of it and provide some references:

20. Has the pilot implementation been evaluated for possible side-effects?

❑Yes ❑ No

If ***Yes***, please give a brief outline of it:

21. If you have written procedures for safety for employees and volunteers within your own group or institution, please explain here how you have assured compliance:

E) Risk assessment

22. Have you performed a risk-assessment concerning breach of privacy and / or breach of safety?

Yes No

If ***Yes***, please give a brief outline of it:

If ***No***, please explain the reasons briefly refer to any corrective actions you will take:

F) Reimbursement

23. Is any reimbursement going to be provided according to your national regulations?

Yes No

If ***Yes***, please give a brief outline of it:

Annex 3: International and European instruments in the field of data protection

The Council of Europe Convention for the protection of individuals with regard to automatic processing of personal data is the first European instrument in this field. It laid down the basic principles of a lawful data processing addressing the threats from the invasion of information systems, such as the data aggregation, at that time. In this respect, it concerns the automatic data processing, although the Member Countries could extend its applicability to non-automatic data processing. Art. 6 states that medical data may not be processed automatically unless domestic law provides appropriate safeguards. The Convention is of limited importance for EU countries after the enactment of the EC Directives on data protection. The Charter of Fundamental Rights in the course independent authority of the respective legal trend dedicates a separate article to the protection of personal data. Article 8 sets out the right to the protection of personal data of an individual and thus the protection of personal data has now an own legal basis apart from the right to respect for an individual's private life and the protection of the human dignity. Art. 8 of the Charter sets out the rules for the legitimate processing of personal data, notably that the processing shall be fair and for pre-specified purposes based on the consent of the data subject or other legitimate basis laid down by law. Reference is furthermore made to two rights of the data subject: the right of access to the data and the right to have it rectified. Finally, Art. 8 sets out the need to control the compliance with the data protection rules.

In 1999 the Council of Europe has adopted the Recommendation on the Guidelines for the protection of privacy in the information highways. These Guidelines may be incorporated in or annexed to codes of conduct of Internet service provider to obtain legal validity. The Recommendation is in line with the EC Data Protection Directives regarding the principles of the lawful data processing, the duties of the Internet service providers and the rights of the data subject. The Recommendation encompasses a series of detailed information what the users and service providers shall do to reduce the risks arising from the Internet. It is worth mentioned that the users are required to use digital signature and encryption techniques. On the other hand, the service providers are required to use certified privacy enhancing technologies, to ensure data confidentiality and integrity as well as logical and physical security of the network and the services provided over the network. The service providers shall also incorporate detailed privacy statements on the web-sites. Finally, the communication of sensitive data, for instance medical data, for marketing purposes requires the previous, informed and explicit consent of the data subject.

The OECD is actively participating in the issues regarding the data protection, the data protection on the Internet as well as the protection of consumer rights with regard to e-commerce. First, OECD issued Guidelines governing the protection of privacy stipulating the fundamental principles (OECD, 1980). In 1998, OECD issued a Recommendation with regard to the implementation of the aforementioned Guidelines on global networks. The Recommendation addresses mainly commercial sites offering various goods and services, such as tourism, air travel ticket sales, finance, etc. It is not legally binding, unless the Internet service providers stipulate this explicitly. Although the Recommendation does not address healthcare applications, its provisions might apply as following:

The Recommendation imposes the obligation to the web-site provider to refer with a hyperlink to the national legislation on data protection and the national Data Protection Authority. Moreover, every Data Protection Authority should be present on the Internet through relevant, well-documented and interactive sites. The web-sites shall also maintain on-line private statements giving details on the kind of data collected, the purpose of, the use of the clickstream data and processing to which they are subject, as well as the opportunity to opt out. In case of on-line payments by cards they should configure their systems in such a way that they ask for the card details once, provided that they store this information in highly secure files on non-networked computers. Warning messages on the risks of the Internet shall be provided in case of processing of confidential data. For confidential data the highest degree of security shall be implemented. The implementation of privacy enhancing technologies is also required. Moreover, web-sites should formally state the acceptance of full responsibility for the security and confidentiality of the personal data collected and processed. With regard to data subjects rights the Recommendation highlights the right to access on-line the information collected and stored directly or indirectly, i.e. clickstreams or purchased profiles.

Annex 4: INFORMED CONSENT

Annex 4.1 Documentation of Consent

Pilot name: _____ (the "Pilot")

Researching entity: _____ ("we", "us", "our")

Researching entity's address: _____

What is the MyCorridor project?

The MyCorridor project is a European Union ("EU") funded project with the aim of facilitating sustainable travel in urban and interurban areas and across borders by replacing vehicle ownership with private vehicle use. The project's objective is to use Mobility as a Service ("MaaS"), to put users at the core of transport services and offer them tailor-made mobility solutions based on each individual's needs. The project intends to use MaaS to integrate various forms of transport into a unified mobility platform; accessible via a single app.

As part of the project, the MyCorridor consortium, which includes 16 research partners across various EU countries (the "Research Partners") and a legal team, will work together to advance the MyCorridor project. Various Research Partners will conduct pilots to research: user behaviour and needs; sustainable intermodal transport; interoperability of data and services; internet-based platforms for information; and booking and travelling and ethical requirements, for the purposes of the MyCorridor project.

By signing the consent form below, you agree to participate in our Pilot, named at the top of this page and detailed below.

What is the purpose of this Pilot?

The purpose of our Pilot is to further the objectives of the MyCorridor project, by
[*to be completed by the relevant pilot entity before submitting to the users*].

Who is conducting the Pilot?

[To be inserted by the relevant pilot entity before submitting to the users – include names of individual researchers, if appropriate].

What type of information will we need to collect from you?

[Before submitting to the users , the relevant pilot entity should insert details of the personal information that they will be asking participants for, e.g. name, address, phone number, age, employment, mobility requirements, access requirements – please note that this may vary for each pilot].

Will my personal information be shared with any third party?

We may need to share information with our Research Partners, the EU Commission or the Innovation and Networks Executive Agency (who assisted with the funding of the MyCorridor project) to assist with the objectives of both the Pilot and the MyCorridor project. All personal information will be anonymised prior to it being shared with any third party.

What will my participation in the Pilot involve?

[To be inserted by the relevant pilot entity before submitting to the users].

What will my participation in the Pilot involve?

[To be inserted by the relevant pilot entity before submitting to the users].

What value can a participant bring to the MyCorridor project?

[To be inserted by the relevant pilot entity before submitting to the users].

What will happen to any information I give you and how will it be stored?

[We will comply with all applicable laws and regulations when it comes to collecting, storing, using and sharing your personal information. All data will be stored anonymously on a password protected computer. No personal data will be centrally stored without first being anonymised. Any hard copy documents containing personal information will be locked in a filing cabinet in our office, at the address printed at the top of this Documentation of Consent. Your personal information will be used to help us achieve the Pilot's objective, as set out in the 'What is the purpose of this Pilot' section above, which will, in turn, further the objectives of the MyCorridor project. We will only share your personal information as described in this Documentation of Consent. After the Pilot is completed and when it is no longer necessary for us to retain your personal information, we shall destroy, as far as reasonably practicable, all such personal information that we hold on you.]

How long will the Pilot last?

[Each pilot entity should insert the estimated duration of their pilot here before submitting to the users].

Who should I contact in relation to the Pilot?

[Each pilot entity should insert the relevant contact's details here before submitting to the users].

What will happen to the results of the Pilot?

[The results of this Pilot may be used by us, and shared and used by, our Research Partners, the European Commission and the Innovation and Networks Executive Agency, at national and international conferences and exhibitions and published in peer-reviewed scientific and academic journals; with a focus on open-access journals. We shall ensure that any personal information you provide us with is anonymised prior to any such use or publication.]

What are the possible benefits of taking part in the Pilot?

[To be inserted by the relevant pilot entity before submitting to the users – please note that this may be different for each pilot.]

Are there any risks?

[To be inserted by the relevant pilot entity before submitting to the users. please note that this may be different for each pilot.]

MyCorridor's Privacy Policy

MyCorridor's Privacy Policy (available [here] [upon request]) contains information about the personal information that we collect from you, and how we collect, store, use and share your personal information. It also sets out your rights to control personal information we hold about you. We will notify you if any changes are made to our Privacy Policy.

Consent Form

Researcher's Name: _____

Participant's Name: _____

Participant's Age Bracket: _____

Participant's Unique Reference Number: _____

Place of Pilot: _____ _____

This part will be filled in by the participant.

The original will be kept be the Researcher; a copy will be given to the participant.

I confirm that I have read and I understand the information in relation to this Pilot.	☐
I have had the opportunity to consider the information provided to me and to ask questions about the Pilot and my participation in the Pilot.	☐
I voluntarily agree to participate in the Pilot.	☐
I understand and agree that any focus groups I participate in may be digitally recorded and transcribed but that any personal information that could be used to identify me will be removed from the transcript.	☐
I understand and agree that the information I give you will be used for the Pilot.	☐
I understand and agree that the information I give you will be used for research, publications, conferences, exhibitions, sharing and archiving, but that my personal information will be anonymised prior to any such use and I will not be identified in any publications, reports or presentations.	
I was informed about procedures regarding confidentiality (e.g. use of names, pseudonyms, anonymisation of personal information, etc.).	☐

I was informed about whom to contact for questions about the research and research participants' rights.	☐
I understand that other researchers will have access to my information only if they agree to preserve the confidentiality of my personal information and only on the terms I have specified in this form.	☐
I have spoken to: Dr./Mr./Ms. ……..	
I understand that I am free to withdraw from the experiment ♦ at any time; and ♦ without having to give a reason for withdrawing.	☐
I understand that the MyCorridor Privacy Policy (available [here] [upon request]) contains information about how I may request access to, and correction of, my personal information; how I may complain about a privacy breach; and how you will deal with any such complaint.	☐
I confirm that I have read, understood and agree to MyCorridor's Privacy Policy in its entirety. If you do not agree to this Privacy Policy in its entirety, you must not participate in this Pilot.	☐
I agree to sign and date this informed Consent Form, along with the Researcher.	☐

Participant:

_____ _____ _____

Name of Participant Signature Date

Researcher:

_____ _____ _____

Name of Researcher Signature Date

Thank you for taking part in this pilot. Your contribution is very much appreciated.

Annex 4.2. Informed Consent Concerning Private Information

A form will be used by MyCorridor researchers who record private information in the course of any evaluation/pilots.

The answers to the questions below will constitute considerable part of the Privacy statement of the MyCorridor platform. The form and format of this statement will be decided later in the project when the Architecture and first platform wireframes will be in place (M24). Please clearly explain to the participant how the following issues regarding privacy are handled related to the experiment at hand:

- What kind of data will be recorded, stored and why?
- Will the data be transferred?
- Data ownership?
- Is the data connected to other information?
- Will the data possibly be commercially exploited?
- Duration of storage?
- Where will the data be stored, - according to which national legislation?
- Who will access the data?
- Who will supervise the data protection?

Annex 5: MyCorridor Questionnaire on Ethics/Legal Issues filled in on MyCorridor Pilot Level

Questionnaire on Ethical and Legal issues filled in for Italy

Should all testing related activities be approved by a local research ethics committee?

☐Yes ☒ No

A) Participants and informed consent

1. **Do you intend to conduct pilots that will require the obtainment of participants' consent?**

   ☒Yes ❑ No

   If ***yes***, briefly explain which specific aspects of the trials you will need to obtain informed consent for:

   ANSWER: Personal data management.

2. **Do you intend to conduct pilots with individuals that might not understand the informed consent form?**

   ❑Yes ☒ No

   If ***yes***, briefly explain the procedures you follow in order to obtain informed consent:

3. **Is the oral consent of a participant in presence of a witness appropriate in accordance with your national legislation?**

   ❑Yes ☒ No

4. **Is there an international or national legislation, which you must follow when performing tests within the MyCorridor project**

   a) involving healthy human participants?

   ☒Yes ❑ No

   If ***Yes***, please give details (reference number and short description of procedure):

   ANSWER: D.lgs 196/2003 and the GDPR (General Data Protection Regulation) (Regulation (EU) 2016/679)

b) involving participants with cognitive impairments / learning difficulties?

❑Yes ☒ No

If ***Yes***, please give details (reference number and short description of procedure):

c) involving *illiterate* or *with co-morbid conditions* participants?

❑Yes ☒ No

If ***Yes***, please give details (reference number and short description of procedure):

B) Ethical control instruments

5. At which level of your organization / enterprise, *ethical controls* are audited?

❑ laboratory or workgroup

❑ division or department

☒ institution

❑ regional

❑ national

6. Is there an ethics controlling body in your region / country?

❑Yes ☒ No

If ***Yes***, please give details about the body relevant for you and the procedure that has to be adhered to in order to obtain ethical approval of experiments:

7. Is there a local ethics controlling committee, that your organisation is obliged to get approval from, for the experimental procedures before beginning with the experiment?

❑Yes ☒ No

If ***Yes***, please give details of the relevant body and shortly describe the specific procedure:

8. **Is there an established ethical control procedure which you must follow before performing tests with**
   a) healthy human participants?

   ☒Yes ❑ No

   If ***Yes***, please give a brief description.

   ANSWER: Inform and obtain authorization for the personal data management (Informed Consent)

b) human participants with cognitive impairments / learning difficulties ?

❑Yes ☒ No

If ***Yes***, please give a brief description.

c) *illiterate* or *with co-morbid conditions* participants?

❑Yes ☒ No

If ***Yes***, please give a brief description.

C) Privacy

9. **Is personal data belonging to individual participants recorded as part of the trial?**

   ☒Yes ❑ No

10. **If so, do you plan to collect also sensible personal data (e.g. health-related information)?**

    ❑Yes ☒ No

11. **Is there an established Data Protection Authority issuing procedures / standards you must follow before performing tests with human participants and their personal / private data?**

    ☒Yes ❑ No

If ***Yes***, please give a brief outline of it: *ANSWER: D.lgs 196/2003*

If ***No***, please explain briefly what corrective actions you will take to ensure privacy of personal data of participants:

12. Do you follow written procedures for protecting privacy?

☒Yes ❑ No

If ***Yes***, please give a brief outline of it:

ANSWER: SWARCO Mizar has established specific procedures for:

1) *digital data protection according to the 2700 standards*
2) *personal data management according to the ISO9001:2015 norm*

If ***No***, please explain the reasons briefly and submit any corrective actions you will take for OC review:

13. Do you follow or are you aware of any official national or international guidelines on protecting privacy?

☒Yes ❑ No

If ***Yes***, please give a brief outline and provide references:
ANSWER: D.lgs 196/2003 and the DGPR (General Data Protection Regulation) (Regulation (EU) 2016/679)

If ***No***, please contact OC.

14. Do you identify persons and their professions who are authorised to have access to the data collected and / or who have access to any data storage devices, both paper-based and electronically?

☒Yes ❑ No

If ***Yes***, please give a brief outline and provide references.

ANSWER: Managing Director of SWARCO Mizar grants by a written assignment specific persons for personal data management

D) Safety

15. Will you provide information to the participants if you become aware of an illness that could create risks to other participants?

☒Yes ❑ No

If ***Yes***, please give a brief outline of it and provide some references:

ANSWER: Exclude immediate the illness by the pilot and in case of occurred risk it will be informed other participants guarantee anyway the protection of personal data of the illness person (anonymity).

16. Is every pilot implementation evaluated for possible side-effects?

☒Yes ❑ No

If ***Yes***, please give a brief outline of it:

ANSWER: at project level KPIs will be defined to assess the improvements and affects of the MyCorridor service provision.

17. Do have written procedures for safety for employees and volunteers within your own group or institution?

☒Yes ❑ No

If ***Yes***, please give a brief outline of it:
ANSWER: for employees company must be compliance with the national law: Dls 81/08.

If ***No***, please explain the reasons briefly or what corrective actions you take:

E) Risk assessment

18. Do you have procedures to perform risk-assessment concerning breach of privacy and / or breach of safety?

☒Yes ☐ No

If ***Yes***, please give a brief outline of it:

ANSWER: SWARCO Mizar has elaborated a document (named DURC) about safety and risk analysis. While privacy issues are managed according to the company quality procedures in line with ISO9001:2015 norm (e.g. Periodic internal Audit and corrective action).

If ***No***, please explain the reasons briefly and refer any corrective actions you will take to OC:

19. Is your organisation insured against risks as a result of breach of privacy and safety?

☒ Yes ❑ No

If ***Yes***, please give a brief outline of it and state the insurer, if possible:

ANSWER: Employees are covered by specific work insurance

If ***No***, please explain the reasons briefly and state who would cover any insurance-related costs:

20. For conducting research and manage the risk, do you need to involve other organisations (unit, division, department etc.) that might have influence on your research activities as well as on your ethical and legal conduct?

❑ Yes ☒ No

If Yes, please give a brief outline of it: -

Questionnaire on Ethical and Legal issues filled in for the Netherlands

Should all testing related activities be approved by a local research ethics committee?

☐Yes ☒ No

A) Participants and informed consent

1. **Do you intend to conduct pilots that will require the obtainment of participants' consent?**

   ❑Yes ☒ No

   If ***yes***, briefly explain which specific aspects of the trials you will need to obtain informed consent for:

   ANSWER: We would like to see whether our customers do follow our advise. .

2. **Do you intend to conduct pilots with individuals that might not understand the informed consent form?**

   ❑ Yes ☒ No

   If ***yes***, briefly explain the procedures you follow in order to obtain informed consent:

   ANSWER: _ We our not able to say whether the consent form can be understood by everybody. Isn't this the same as with Google and Apple. No one reads them...and then clicks 'Yes'.

3. **Is the oral consent of a participant in presence of a witness appropriate in accordance with your national legislation?**

   ☒Yes ❑ No

4. **Is there an international or national legislation, which you must follow when performing tests within the MyCorridor project**

   a) involving healthy human participants?

   ☒Yes ❑ No

If ***Yes***, please give details (reference number and short description of procedure):

ANSWER: Dutch Medical Research Involving Human Subjects Act.

b) involving participants with cognitive impairments / learning difficulties?

☒Yes ❑ No

If ***Yes***, please give details (reference number and short description of procedure):

ANSWER: Dutch Medical Research Involving Human Subjects Act.

c) involving *illiterate* or *with co-morbid conditions* participants?

☒ Yes ❑ No

If ***Yes***, please give details (reference number and short description of procedure):

ANSWER: Dutch Medical Research Involving Human Subjects Act.

B) Ethical control instruments

5. At which level of your organization / enterprise, *ethical controls* are audited?

☒ laboratory or workgroup

❑ division or department

❑ institution

❑ regional

❑ national

6. Is there an ethics controlling body in your region / country?

☒ Yes ❑ No

If ***Yes***, please give details about the body relevant for you and the procedure that has to be adhered to in order to obtain ethical approval of experiments:

ANSWER: The Central Committee on Research Involving Human Subjects

7. **Is there a <u>local</u> ethics controlling committee, that your organisation is obliged to get approval from, for the experimental procedures before beginning with the experiment?**

❑Yes ☒ No

If ***Yes***, please give details of the relevant body and shortly describe the specific procedure:

8. **Is there an established ethical control procedure which you must follow before performing tests with**
a) healthy human participants?

☒Yes ❑ No

If ***Yes***, please give a brief description.

<u>ANSWER: The Central Committee on Research Involving Human Subjects.</u>

b) human participants with cognitive impairments / learning difficulties ?

☒ Yes ❑ No

If ***Yes***, please give a brief description.

<u>ANSWER: The Central Committee on Research Involving Human Subjects.</u>

c) *illiterate* or *with co-morbid conditions* participants?

☒ Yes ❑ No

If ***Yes***, please give a brief description.

<u>ANSWER: The Central Committee on Research Involving Human Subjects.</u>

C) Privacy

9. **Is personal data belonging to individual participants recorded as part of the trial?**

☒Yes ❑ No

10. **If so, do you plan to collect also sensible personal data (e.g. health-related information)?**

❑Yes ☒ No

11. Is there an established Data Protection Authority issuing procedures / standards you must follow before performing tests with human participants and their personal / private data?

☒Yes ❑ No

If ***Yes***, please give a brief outline of it:

ANSWER: See Authoriteit persoonsgegevens (autoriteitpersoonsgegevens.nl/en)

If ***No***, please explain briefly what corrective actions you will take to ensure privacy of personal data of participants:

12. Do you follow written procedures for protecting privacy?

☒Yes ❑ No

If ***Yes***, please give a brief outline of it:

ANSWER: See Authoriteit persoonsgegevens (autoriteitpersoonsgegevens.nl/en)

If ***No***, please explain the reasons briefly and submit any corrective actions you will take for OC review:

13. Do you follow or are you aware of any official national or international guidelines on protecting privacy?

☒Yes ❑ No

If ***Yes***, please give a brief outline and provide references:

ANSWER: See Authoriteit persoonsgegevens (autoriteitpersoonsgegevens.nl/en)

If ***No***, please contact OC.

14. Do you identify persons and their professions who are authorised to have access to the data collected and / or who have access to any data storage devices, both paper-based and electronically?

❑Yes ☒ No

If ***Yes***, please give a brief outline and provide references.

D) Safety

15. Will you provide information to the participants if you become aware of an illness that could create risks to other participants?

❑Yes ☒ No

If ***Yes***, please give a brief outline of it and provide some references:

16. Is every pilot implementation evaluated for possible side-effects?

❑Yes ☒ No

If ***Yes***, please give a brief outline of it:

17. Do have written procedures for safety for employees and volunteers within your own group or institution?

☒Yes ❑ No

If ***Yes***, please give a brief outline of it:

ANSWER: VCA (Veiligheid Gezondheid Milieu) Checklist Aannemers. Checklist to establish a safe workspace on worksites.

If ***No***, please explain the reasons briefly or what corrective actions you take:

E) Risk assessment

18. Do you have procedures to perform risk-assessment concerning breach of privacy and / or breach of safety?

❑ Yes ☒ No

If ***Yes***, please give a brief outline of it:

If ***No***, please explain the reasons briefly and refer any corrective actions you will take to OC:

ANSWER: We have never needed to do this. We currently do not store private data of individuals.

19. Is your organisation insured against risks as a result of breach of privacy and safety?

❑ Yes ☒ No

If ***Yes***, please give a brief outline of it and state the insurer, if possible:

If ***No***, please explain the reasons briefly and state who would cover any insurance-related costs:

ANSWER: Currently we do not store sensitive data. The data that is storen is mainly sourced from open-data.

20. For conducting research and manage the risk, do you need to involve other organisations (unit, division, department etc.) that might have influence on your research activities as well as on your ethical and legal conduct?

❑ Yes ☒ No

If Yes, please give a brief outline of it: -

Questionnaire on Ethical and Legal issues filled in for Czech Republic

Should all testing related activities be approved by a local research ethics committee?

☐Yes ☒ No

A) Participants and informed consent

1. **Do you intend to conduct pilots that will require the obtainment of participants' consent?**

   ☒Yes ❑ No

   If ***yes***, briefly explain which specific aspects of the trials you will need to obtain informed consent for:

   ANSWER: Personal data and audio records management.

2. **Do you intend to conduct pilots with individuals that might not understand the informed consent form?**

   ❑ Yes ☒ No

   If ***yes***, briefly explain the procedures you follow in order to obtain informed consent:

3. **Is the oral consent of a participant in presence of a witness appropriate in accordance with your national legislation?**

   ☒ Yes ❑ No

4. **Is there an international or national legislation, which you must follow when performing tests within the MyCorridor project**

   a) involving healthy human participants?

   ☒Yes ❑ No

   If ***Yes***, please give details (reference number and short description of procedure):

   ANSWER: the GDPR (General Data Protection Regulation) (Regulation (EU) 2016/679) GDPR + local legislation, however in case of our testing we do not plan to collect any data which would violate any of them

b) involving participants with cognitive impairments / learning difficulties?

❑Yes ☒ No

If ***Yes***, please give details (reference number and short description of procedure):

c) involving *illiterate* or *with co-morbid conditions* participants?

❑Yes ☒ No

If ***Yes***, please give details (reference number and short description of procedure):

B) Ethical control instruments

5. At which level of your organization / enterprise, *ethical controls* are audited?

❑ laboratory or workgroup

❑ division or department

☒ institution

❑ regional

❑ national

6. Is there an ethics controlling body in your region / country?

❑Yes ☒ No

If ***Yes***, please give details about the body relevant for you and the procedure that has to be adhered to in order to obtain ethical approval of experiments:

7. Is there a local ethics controlling committee, that your organisation is obliged to get approval from, for the experimental procedures before beginning with the experiment?

❑Yes ☒ No

If ***Yes***, please give details of the relevant body and shortly describe the specific procedure:

8. **Is there an established ethical control procedure which you must follow before performing tests with**
   a) healthy human participants?

   ❑Yes ☒ No

   If ***Yes***, please give a brief description.

   ANSWER: Inform and obtain authorization for the personal data management (Informed Consent)

b) human participants with cognitive impairments / learning difficulties ?

❑Yes ☒ No

If ***Yes***, please give a brief description.

c) *illiterate* or *with co-morbid conditions* participants?

❑Yes ☒ No

If ***Yes***, please give a brief description.

C) Privacy

9. **Is personal data belonging to individual participants recorded as part of the trial?**

☒Yes ❑ No

10. **If so, do you plan to collect also sensible personal data (e.g. health-related information)?**

❑Yes ☒ No

11. **Is there an established Data Protection Authority issuing procedures / standards you must follow before performing tests with human participants and their personal / private data?**

☒Yes ❑ No

If ***Yes***, please give a brief outline of it: *ANSWER: ÚOOÚ (the office for personal data protection) requires registration, but in case of our experiment we do not plan to collect any data that require this kind of registration to ÚOOÚ*

If ***No***, please explain briefly what corrective actions you will take to ensure privacy of personal data of participants:

12. Do you follow written procedures for protecting privacy?

☒Yes ❑ No

If ***Yes***, please give a brief outline of it:

ANSWER: CHAPS is certified accordingly to ČSN EN ISO 9001:2009 norm

If ***No***, please explain the reasons briefly and submit any corrective actions you will take for OC review:

13. Do you follow or are you aware of any official national or international guidelines on protecting privacy?

☒Yes ❑ No

If ***Yes***, please give a brief outline and provide references:

ANSWER: GDPR (General Data Protection Regulation) (Regulation (EU) 2016/679) GDPR + local legislation, however in case of our testing we do not plan to collect any data which would violate any of them

If ***No***, please contact OC.

14. Do you identify persons and their professions who are authorised to have access to the data collected and / or who have access to any data storage devices, both paper-based and electronically?

☒Yes ❑ No

If ***Yes***, please give a brief outline and provide references.

ANSWER: Only limited number of persons (authorised by company management).

D) Safety

15. Will you provide information to the participants if you become aware of an illness that could create risks to other participants?

☒Yes ❑ No

If ***Yes***, please give a brief outline of it and provide some references:

ANSWER: Exclude immediate the illness by the pilot and in case of occurred risk it will be informed other participants guarantee anyway the protection of personal data of the illness person (anonymity).

16. Is every pilot implementation evaluated for possible side-effects?

❑Yes ☒ No

If ***Yes***, please give a brief outline of it:

17. Do have written procedures for safety for employees and volunteers within your own group or institution?

☒Yes ❑ No

If ***Yes***, please give a brief outline of it:
ANSWER: Common procedures for an IT company in line with local legislation

If ***No***, please explain the reasons briefly or what corrective actions you take:

E) Risk assessment

18. Do you have procedures to perform risk-assessment concerning breach of privacy and / or breach of safety?

☒Yes ☐ No

If ***Yes***, please give a brief outline of it:

ANSWER: According to local legislation..

If ***No***, please explain the reasons briefly and refer any corrective actions you will take to OC:

19. Is your organisation insured against risks as a result of breach of privacy and safety?

☒ Yes ❑ No

If ***Yes***, please give a brief outline of it and state the insurer, if possible:

ANSWER: We have a company insurance covering this kind of risks, insurer is CHUBBS (https://www2.chubb.com/)

If ***No***, please explain the reasons briefly and state who would cover any insurance-related costs:

20. For conducting research and manage the risk, do you need to involve other organisations (unit, division, department etc.) that might have influence on your research activities as well as on your ethical and legal conduct?

❑ Yes ☒ No

If Yes, please give a brief outline of it: -

Questionnaire on Ethical and Legal issues for Greece

Should all testing related activities be approved by a local research ethics committee?

☒Yes ❑ No

A)Participants and informed consent

1. **Do you intend to conduct pilots that will require the obtainment of participants' consent?**
   ☒Yes ❑ No

   If ***yes***, briefly explain which specific aspects of the trials you will need to obtain informed consent for:

   ANSWER: We need to obtain informed consent for both evaluation phases because we will collect, store, treat, analyse and report data from recruited and engaged users.

2. **Do you intend to conduct pilots with individuals that might not understand the informed consent form?**
   ❑Yes ☒ No

   If ***yes***, briefly explain the procedures you follow in order to obtain informed consent: _____

3. **Is the oral consent of a participant in presence of a witness appropriate in accordance with your national legislation?**
   ☒Yes

4. **Is there an international or national legislation, which you must follow when performing tests within the MyCorridor project**
   a) involving healthy human participants?

   ☒Yes ❑ No

   If ***Yes***, please give details (reference number and short description of procedure):

   ANSWER: Below you may find National Laws -apart from international/European legislation and guidelines as these have been defined in Section 5 of MyCorridor proposal (Part B Sections 4-5).

   1. v. 2472/1997, 2819/2000, 2915/2001, 3235/2004, 3471 /2006
   Protection of personal data collected during trials/ tests.

   2. v. 927/1979, 3304/2005- *Racism and* ***v. 3536/2007, 3613/2007*** *– Immigrants and foreigners*

Equal treatment of participants regardless their age, gender, race or minority group they belong to, ethnicity, religion, sexual preferences, disability, language and socio-economic status.

Legislation related to data protection and security can be found in the following links:

3. ***v.2472/1997 – Individual Protection and Personal Data treatment*** *(http://www.dpa.gr/portal/page?_pageid=33,123437&_dad=portal&_schema=PORTAL)*

b) involving participants with cognitive impairments / learning difficulties?

☒Yes ❑No

If ***Yes***, please give details (reference number and short description of procedure):

ANSWER: United Nations Convention on the Rights of Persons with Disabilities

(described in detail here: http://ec.europa.eu/social/main.jsp?catId=1138&langId=en)

c) involving *illiterate* or *with co-morbid conditions* participants?

☒Yes ❑ No

If ***Yes***, please give details (reference number and short description of procedure):

ANSWER: Same above.

B) Ethical control instruments

5. At which level of your organization / enterprise, *ethical controls* are audited?

❑ laboratory or workgroup

❑ division or department

☒ institution/ organization

❑ regional

❑ national

6. Is there an ethics controlling body in your region / country?

❑Yes ☒No

If ***Yes***, please give details about the body relevant for you and the procedure that has to be adhered to in order to obtain ethical approval of experiments:

7. **Is there a <u>local</u> ethics controlling committee, that your organisation is obliged to get approval from, for the experimental procedures before beginning with the experiment?**
☒Yes ❑ No

If ***Yes***, please give details of the relevant body and shortly describe the specific procedure:

<u>ANSWER: As above. We submit an ethics application for approval at CERTH Bioethics committee.</u>

8. **Is there an established ethical control procedure which you must follow before performing tests with**
a) healthy human participants?

☒Yes ❑ No

If ***Yes***, please give a brief description.

<u>ANSWER: We submit an ethics application to the CERTH Ethics committee that includes the following:</u>

<u>Project description, detailed pilot plan, descriptions of systems and data collected, data privacy and anonymization procedure, informed consent and all the evaluation material that will be administered. In addition, any other relevant information that does not include in these categories but are essential for the pilot conduction is annexed.</u>

b) human participants with cognitive impairments / learning difficulties?

☒Yes ❑ No

If ***Yes***, please give a brief description.

<u>ANSWER: See answer in Q. 7 and additionally we must submit the consent form in format that is comprehensible by the participant if the person does not require a legal representative. We do not involve participants who cannot consent and need consent by the legal representative/ care provider.</u> [3]

c) *illiterate* or *with co-morbid conditions* participants?

☒Yes ❑ No

If ***Yes***, please give a brief description.

<u>ANSWER: See answer in Q.7. Oral consent is obtained and relevant form is prepared and submitted for approval to the Ethics committee at CERTH. People with co-morbid conditions fall into the same conditions as are applicable for healthy participants.</u>

[3] *The answer refers to CERTH existing procedures and guidelines in recruiting and treating participants from these two vulnerable groups but it is not envisaged to be applicable in MyCorridor evaluation activities. In Greece, CERTH has experience and procedures for recruiting as well as conducting research with people coming from these groups.*

*C) **Privacy***

9. Is personal data belonging to individual participants recorded as part of the trial?
❑Yes ☒ No

ANSWER: Personal data will be collected and stored only if participants agree to be added to the recruitment database that is not stored with any data related to project pilots and experiments. They are kept and stored separately and only one person has access to them. This information is added in the consent form.

10. If so, do you plan to collect also sensible personal data (e.g. health-related information)?
❑Yes ☒ No

ANSWER: No, the same process as in Q. 9 are applicable. These data are used only for clustering users in categories and they are not related to any other personal information because they are coded.

11. Is there an established Data Protection Authority issuing procedures / standards you must follow before performing tests with human participants and their personal / private data?
☒Yes ❑ No

If ***Yes***, please give a brief outline of it:

ANSWER: In addition, depending on the nature of the experiment/trial/pilot, we often apply to the National Data Protection Authority, i.e., when we collect personal data. Official approval is required before we conduct tests.

If ***No***, please explain briefly what corrective actions you will take to ensure privacy of personal data of participants:

12. Do you follow written procedures for protecting privacy?
☒Yes ❑ No

If ***Yes***, please give a brief outline of it:

ANSWER: Each participant is allocated with a code that does not contain and/or reveal any personal information. The allocation takes place during recruitment. Therefore, data collection for each participant is only related to the participant code and in no way to the person themselves. The recruitment officer has only access to the database and does not know which code is allocated to each person as they are randomly allocated using an Excel tool. All files are password protected and stored locally. Pilot data and personal information data are not stored together and are not accessed by the same people.

If ***No***, please explain the reasons briefly and submit any corrective actions you will take for OC review:

13. **Do you follow or are you aware of any official national or international guidelines on protecting privacy?**
☒Yes ❑ No

If ***Yes***, please give a brief outline and provide references:

ANSWER: Data Protection legislation is relevant, apart from the international and European legislation and guidelines mentioned in Section 5 of MyCorridor proposal (Part B Sections 4-5 document).

If ***No***, please contact OC.

14. **Do you identify persons and their professions who are authorised to have access to the data collected and / or who have access to any data storage devices, both paper-based and electronically?**
☒Yes ❑ No

If ***Yes***, please give a brief outline and provide references.

ANSWER: Please refer to answer in Q.12.

D) Safety

15. **Will you provide information to the participants if you become aware of an illness that could create risks to other participants?**
❑Yes ☒ No

If ***Yes***, please give a brief outline of it and provide some references:

ANSWER: The tests and pilots conducted at CERTH do not involve any of such risks. No such issue is anticipated/ expected for MyCorridor project.

16. **Is every pilot implementation evaluated for possible side-effects?**
☒Yes ❑ No

If ***Yes***, please give a brief outline of it:

ANSWER: Any system and pilot implementation is validated and pre-tested before any tests takes place to ensure no risk or side-effects are probable or possible. No such issue is anticipated/ expected for MyCorridor project.

17. **Do have written procedures for safety for employees and volunteers within your own group or institution?**
☒Yes ❑ No

If ***Yes***, please give a brief outline of it:

ANSWER: An internal document exists that describes the procedure and the organizational structure of the committee for health and safety within CERTH. Unfortunately, it is in Greek.

If ***No***, please explain the reasons briefly or what corrective actions you take:

E) Risk assessment

18. Do you have procedures to perform risk-assessment concerning breach of privacy and / or breach of safety?

☒Yes ☐ No

If ***Yes***, please give a brief outline of it:

ANSWER: Yes, please also refer to answer in Q.16 but the breach of privacy exists on institutional level and not on organizational level. Breach of safety exists on organizational level (i.e. CERTH) and includes institutional practices (i.e. HIT).

If ***No***, please explain the reasons briefly and refer any corrective actions you will take to OC:

19. Is your organisation insured against risks as a result of breach of privacy and safety?

☒Yes ☐ No

If ***Yes***, please give a brief outline of it and state the insurer, if possible:

ANSWER: Employees and volunteers are insured for breach of health and safety but not for privacy only when they are within CERTH premises. Privacy protocol is applicable on institutional level.

If ***No***, please explain the reasons briefly and state who would cover any insurance-related costs:

20. For conducting research and manage the risk, do you need to involve other organisations (unit, division, department etc.) that might have influence on your research activities as well as on your ethical and legal conduct?
☒Yes ☐ No

If Yes, please give a brief outline of it:

ANSWER: We have to involve the Ethics committee and the legal department of CERTH for ethical approval and legal consultation on research related activities. The latter is necessary only in cases and testing that we have identified any legal relevant potential implications to the user, the institute/organisation and/ or the consortium.

Questionnaire on Ethical and Legal issues for Austria

Should all testing related activities be approved by a local research ethics committee?

☐Yes ☒ No

A) Participants and informed consent

1. **Do you intend to conduct pilots that will require the obtainment of participants' consent?**
   ☒Yes ❑ No

   If ***yes***, briefly explain which specific aspects of the trials you will need to obtain informed consent for:

   ANSWER: for the focus groups that are carried out within WP 1 (A1.1) and within the frame of the pilots that will take place in Salzburg (WP 6)

2. **Do you intend to conduct pilots with individuals that might not understand the informed consent form?**
   ❑Yes ☒ No

   If ***yes***, briefly explain the procedures you follow in order to obtain informed consent: _____

3. **Is the oral consent of a participant in presence of a witness appropriate in accordance with your national legislation?**

   ❑Yes ☒ No

4. **Is there an international or national legislation, which you must follow when performing tests within the MyCorridor project**
   a) involving healthy human participants?

   ☒Yes ❑ No

   If ***Yes***, please give details (reference number and short description of procedure):

   ANSWER: Data Protection Act 2000 (DSG 2000), BGBl. I No. 165/1999 as amended, from May 2018 onwards the Data Protection Act 2018 will be in place. The planned activities must be submitted to and approved by the Data Protection Authority.

b) involving participants with cognitive impairments / learning difficulties?

☐Yes ☒No

If ***Yes***, please give details (reference number and short description of procedure):

Note: Tests with cognitive impairments/learning difficulties are not planned within the frame of the focus groups and pilots in Salzburg. Apart from that, the Data Protection Act applies for all human participants.

c) involving *illiterate* or *with co-morbid conditions* participants?

☐Yes ☒ No

If ***Yes***, please give details (reference number and short description of procedure):

Note: Tests with illiterate or with co-morbid conditions participants are not planned within the frame of the focus groups and pilots in Salzburg. Apart from that, the Data Protection Act applies for all human participants.

B) Ethical control instruments

5. At which level of your organization / enterprise, *ethical controls* are audited?

❑ laboratory or workgroup

❑ division or department

☒ institution/ organization

❑ regional

❑ national

Note: Ethical controls are only carried out on request at the ethics committee in Salzburg. Requests from Salzburg Research in the past have be done at project level.

6. Is there an ethics controlling body in your region / country?

☒Yes ☐No

If ***Yes***, please give details about the body relevant for you and the procedure that has to be adhered to in order to obtain ethical approval of experiments:

ANSWER: the Ethics committee for the province of Salzburg is located at the Paris-Lodron University of Salzburg. The Ethics Committee is responsible for the assessment of clinical trials according to the German Medicines Act (AMG), the Medical Devices Act (MPG), the Genetic Engineering Act (GTG) and

new medical methods as well as applied medical research and nursing research projects according to the Salzburg Hospital Act 2000 (SKAG). Conducting ethical research on other topics needs to be requested, i.e. Salzburg Research would have to submit a request at the ethics committee if they would investigate the relevant aspects from the MyCorridor project.

7. Is there a local ethics controlling committee, that your organisation is obliged to get approval from, for the experimental procedures before beginning with the experiment?

☐Yes ☒ No

If ***Yes***, please give details of the relevant body and shortly describe the specific procedure:

8. Is there an established ethical control procedure which you must follow before performing tests with
a) healthy human participants?

☐Yes ☒ No

If ***Yes***, please give a brief description.

b) human participants with cognitive impairments / learning difficulties?

☐Yes ☒ No

If ***Yes***, please give a brief description.

c) *illiterate* or *with co-morbid conditions* participants?

☐Yes ☒ No

If ***Yes***, please give a brief description.

C) Privacy

9. Is personal data belonging to individual participants recorded as part of the trial?

☒Yes ☐ No

10. If so, do you plan to collect also sensible personal data (e.g. health-related information)?

❑Yes ☒ No

11. Is there an established Data Protection Authority issuing procedures / standards you must follow before performing tests with human participants and their personal / private data?

☒Yes ❑ No

If ***Yes***, please give a brief outline of it:

ANSWER: The Data Protection Act 2000 (DSG 2000), BGBl. I No. 165/1999 as amended, is the current Austrian data protection law and thus the most important legal regulation on data protection in Austria. From May 2018 onwards the Data Protection Act 2018 will supersede the current act.

If ***No***, please explain briefly what corrective actions you will take to ensure privacy of personal data of participants:

12. Do you follow written procedures for protecting privacy?

☒Yes ❑ No

If ***Yes***, please give a brief outline of it:

ANSWER: Procedures in the quality management system (ISO 9001:2015) define how sensible data are stored and who has access to that data.

If ***No***, please explain the reasons briefly and submit any corrective actions you will take for OC review:

13. Do you follow or are you aware of any official national or international guidelines on protecting privacy?

☒Yes ❑ No

If ***Yes***, please give a brief outline and provide references:

ANSWER: We are aware of the Data Protection Act 2000 respectively the upcoming Data Protection Act 2018 and the General Data Protection Regulation (GDPR).

If ***No***, please contact OC.

14. Do you identify persons and their professions who are authorised to have access to the data collected and / or who have access to any data storage devices, both paper-based and electronically?

☐Yes ☒ No

If ***Yes***, please give a brief outline and provide references.

D) Safety

15. Will you provide information to the participants if you become aware of an illness that could create risks to other participants?

❑Yes ☒ No

NOTE: Not relevant for MyCorridor focus groups and pilots.

If ***Yes***, please give a brief outline of it and provide some references:

16. Is every pilot implementation evaluated for possible side-effects?

☒Yes ❑ No

If ***Yes***, please give a brief outline of it:

ANSWER: Salzburg Research will evaluate what might be possible side-effects, e.g. if the provided traveller information contains erroneous data.

17. Do have written procedures for safety for employees and volunteers within your own group or institution?

☒Yes ❑ No

If ***Yes***, please give a brief outline of it:

ANSWER: Salzburg Research has first-aid-measures and firefall-measures in place.

If ***No***, please explain the reasons briefly or what corrective actions you take:

E) Risk assessment

18. Do you have procedures to perform risk-assessment concerning breach of privacy and / or breach of safety?

☒Yes ☐ No

If ***Yes***, please give a brief outline of it:

ANSWER: Chances and risks concerning the risk-assessment of breach of privacy and/or breach of safety are depicted in the quality management system of Salzburg Research. Salzburg Research is certified according to the new standard ISO 9001: 2015.

If ***No***, please explain the reasons briefly and refer any corrective actions you will take to OC:

19. Is your organisation insured against risks as a result of breach of privacy and safety?
☒Yes ☐ No

If ***Yes***, please give a brief outline of it and state the insurer, if possible:

ANSWER: Salzburg Research is insured over the office of the Salzburg provincial government (liability insurance). However, the insurance does not cover all risks completely.

If ***No***, please explain the reasons briefly and state who would cover any insurance-related costs:

20. For conducting research and manage the risk, do you need to involve other organisations (unit, division, department etc.) that might have influence on your research activities as well as on your ethical and legal conduct?
☐Yes ☒ No

If Yes, please give a brief outline of it: