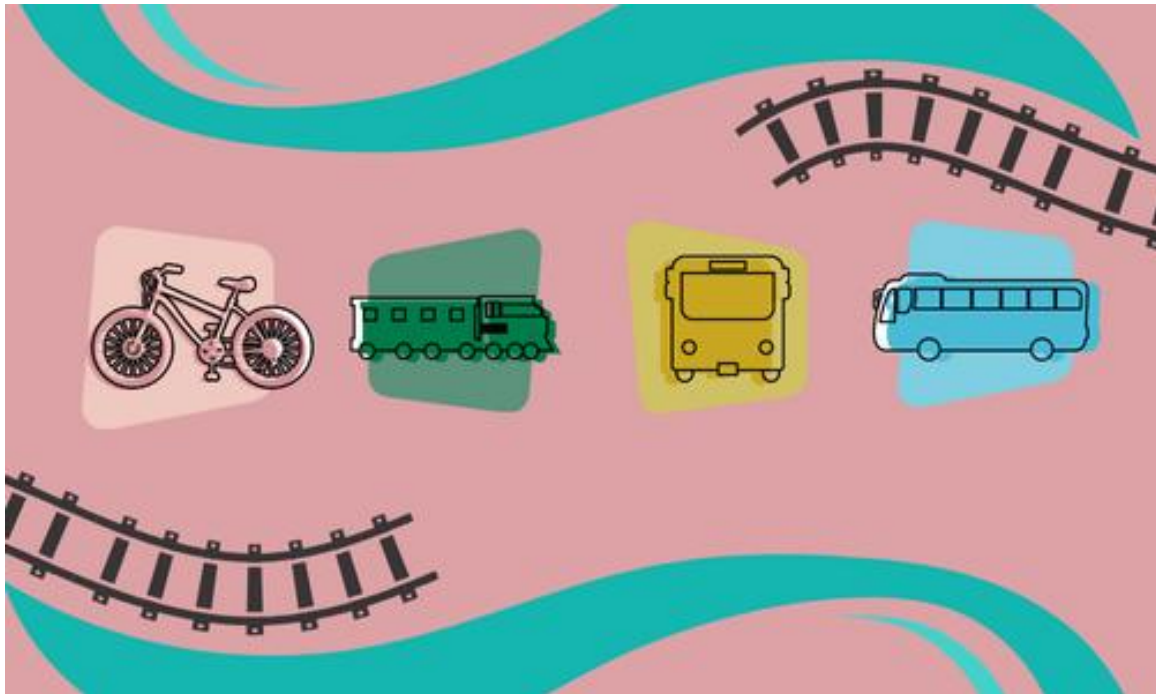




D8.2 – Report on ethical compliance strategies



Multimodal Optimisation leveraging Data Acquisition from Local Stakeholders towards a Holistic Improvement of Freight and People Transport

Project Information

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Nature of the deliverable		
R	Document, report (excluding the periodic and final reports)	X
DEM	Demonstrator, pilot, prototype, plan designs	
DEC	Websites, patents filing, press & media actions, videos, etc.	
DATA	Data sets, microdata, etc.	
DMP	Data management plan	
ETHICS	Deliverables related to ethics issues	X
SECURITY	Deliverables related to security issues	
OTHER	Software, technical diagram, algorithms, models, etc.	

Dissemination level		
PU	Public, fully open, e.g. web (Deliverables flagged as public will be automatically published in CORDIS project's page)	X
SEN	Sensitive, limited under the conditions of the Grant Agreement	

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1 PROJECT ABSTRACT

The vision of **MODALSHIFT** lies in the creation of a transport network and traffic management optimisation framework, trusted and valuable for local stakeholders, that bridges the data from infrastructures, logistics and mobility operators.

New IoT devices - a smart box enabling Capacity-as-a-Service, and a e-subscription device for public transport access for vulnerable people, will increase the sources for data collection. A mobility data space, associated to novel geolocation data anonymisation, will be set up in the 3 Case Studies (Bulgaria, Italy, Spain) to ensure trusted and secure data exchange between data providers and users. This multisource data will enhance traffic state forecasting and increase the detection rate of events by 15%. On this basis, predictive and prescriptive analytics and synchromodality-based scenarios, tested in digital twins and early pilots, will identify optimal actions of transport stakeholders for adjusting their operations, towards a reduction of 25% of the interconnection or transshipment delays.

Agent-based modelling will identify how a modal shift towards low-carbon, active and shared mobility services can be acceptable by end-users and support a reshape of the public transport services and the use of urban space. A multimodal traffic management platform will orchestrate, upon the data space, the cooperation of stakeholders at network and multimodal hub scales. It enables the connection of dynamic optimisation algorithms to operational drivers' tool for mobility operators, and of static models to visual interface for transport planners. The determination of governance models, values for each stakeholder, dynamic pricing and business models, will steer the participation of 8 stakeholders for each Case Study in the multimodal traffic management system.

With this approach, MODALSHIFT stimulates new uses of the transport network to reduce traffic congestion for low-carbon and inclusive mobility, avoiding pernicious rebound effects.

2 EXECUTIVE SUMMARY

This deliverable (D8.2 – Report on ethical compliance strategies) sets out MODALSHIFT's governance, procedures and evidence base to ensure that all research, data and AI-related activities are conducted lawfully, ethically and transparently across the three case studies. The main purpose of this document is to establish a clear ethical framework and guiding principles for the project, within the ethical and regulatory framework of MODALSHIFT (Horizon Europe ethics obligations, GDPR, EU AI Act).

To this end, it:

- Establishes an Ethics Committee/Group with a defined mission, composition and responsibilities; links to related WPs and deliverables have been formalised (e.g., D2.1 Data Management Plan; anonymisation processes).
- Defines the ethical governance framework, including an Ethics Self-Assessment recap, an initial Ethics Risk Assessment (ERA) template, and an Ethical Requirements Register to track scope, safeguards, responsibilities and status.
- Prepares the AI strategy and evaluation methodology, aligning with the Ethics Guidelines for Trustworthy AI (AI HLEG/ALTAI) and mapping project AI uses to the EU AI Act through a stepwise procedure (scope, role, risk classification, obligations, controls, and evidence).
- Designs a training plan (two workshops on anonymisation and responsible AI practices) to build shared capability on GDPR-compliant data handling and privacy-by-design.

This is the **first version** of the Ethical Plan. It is a **living framework and document**, which will be iteratively refined as appropriate, alongside pilot design and implementation, AI iterations, and emerging ethical considerations. The

approach emphasizes proportionality (risk-based controls), transparency (complete records), and continuous improvement (monitor–review cycles) to support safe, inclusive, and trustworthy multimodal mobility innovation.

2.1 INTENDED AUDIENCE

This document mainly focuses on the Project Ethics Committee, as well as to those involved in the management, supervision, and assurance of ethical compliance. It is also intended for all responsible partners and team members who handle or use data, models, systems, or services that may be subject to ethical, privacy, or AI-related considerations. Finally, it is addressed to the entire consortium so that they are aware of the ethical aspects that must be complied with throughout the project.

The overall purpose is to provide guidance for the management, monitoring, and verification of ethical compliance across all project activities, in alignment with the Ethical and Legal Framework of MODALSHIFT, AI Act, and other relevant ethical frameworks.

2.2 DESCRIPTION OF THE MAIN ACTIVITIES

This document mainly address:

- Establishment of the Ethics Committee, with clearly defined roles, responsibilities, and obligations.
- Initial definition of the project's ethical requirements in line with EU standards.
- Initial AI development strategy, including an assessment of alignment with the EU AI Act.
- A plan for documentation and iterative updates as the project progresses.

It consolidates the consortium's Ethics Requirements (H/POPD/NEC/AI), aligns the AI Strategy with the EU AI Act and Trustworthy AI guidelines, and sets out a living framework for risk assessment, documentation, training, and continuous improvement from M6 to M42.

3 ABBREVIATIONS

Table 1: List of abbreviations

Abbreviation	Definition
AI	Artificial Intelligence
AI HLEG	High-Level Expert Group on AI
ALTAI	Application of the Assessment List for Trustworthy AI
CFR	Charter of Fundamental Rights of the European Union
DMP	Data Management Plan
DPA	Data Processing Agreement
DPIA	Data Protection Impact Assessment
DTA	Data Transfer Agreements
EDPB	European Data Protection Board
ESA	Ethics Self-Assessment
ERA	Ethics Risk Assessment
EU	European Union
GDPR	General Data Protection Regulation
AI HLEG	High-Level Expert Group on AI
MGA	Model Grant Agreement
NEC	Non-EU Countries
POPD	Processing Of Personal Data
SCC	Standard Contractual Clause
WP	Work Package

4 INTRODUCTION

This document outlines the Ethics Strategy Plan for the project MODALSHIFT. Our consortium is committed to upholding ethical standards in all research and innovation activities. The project involves the processing of personal data and the possible development/use of Artificial Intelligence (AI) systems, which implies the need for a proactive and structured approach to ethics and regulatory compliance.

The main purpose of this document is to establish a clear ethical framework and guidelines for the project. Among other things, this plan:

- Defines governance structures, roles, and responsibilities for ethical oversight.
- Ensures compliance with key EU regulations, including the General Data Protection Regulation (GDPR) and the EU AI Act.
- Outlines procedures for identifying, assessing, and mitigating ethical risks throughout the project lifecycle.
- Provides a transparent framework for all consortium partners to follow.
- Addresses ethics obligations for AI and non-AI developments.

The Ethics Strategy Plan will be primarily implemented and overseen by the Ethics Committee, which will coordinate, manage, and supervise ethical matters, ensuring compliance with all ethical requirements and addressing any related issues throughout the project.

This is a **living document** and will be reviewed and updated as needed until the end of the project.

4.1 ETHICAL AND REGULATORY FRAMEWORK OF MODALSHIFT

The MODALSHIFT project is committed to following the ethical and legal principles laid out in Horizon Europe, specifically Article 19 of Regulation (EU) 2021/695 and Article 14 of the Model Grant Agreement (MGA).

In line with Article 19, MODALSHIFT ensures that all research and innovation activities are conducted in accordance with fundamental ethical principles and relevant legislation. Furthermore, as required by Article 14 of the MGA, MODALSHIFT pledges to uphold the highest ethical standards throughout the entire duration of the project. These principles include respect for human dignity, freedom, democracy, equality, the rule of law, and the rights of individuals, including the rights of vulnerable groups.

Aligned with the ethical framework of Horizon Europe, the MODALSHIFT consortium commits to safeguarding key rights and values during the development and deployment of its multimodal transport services, data analytics, and digital solutions. These include the principle of proportionality, the right to privacy, the protection of personal data, the right to physical and mental integrity, the principle of non-discrimination, and the obligation to protect the environment and public health. These principles are embedded in the project's design and will be closely monitored throughout the implementation of the three pilot cases in Spain, Italy, and Bulgaria.

Therefore, the following documents serve as key references and background for the ethical and legal foundation of the project:

- **Ethical principles of Horizon Europe** (Article 19 - Regulation (EU) 2021/695)
- **The European Convention on Human Rights and its Protocol, and The Charter of Fundamental Rights of the European Union (CFR)** (2012/C 326/02): CFR encompasses the rights guaranteed by the EU: dignity, freedoms, equality, solidarity, citizens' rights, and justice.
- **The European Code of Conduct for Research Integrity** (ALLEA, 2023 update): European framework of good research practices. It defines integrity principles including reliability, honesty, respect, and responsibility, and provides research guidelines in the contexts such as research environment, training,

supervision and mentoring, research procedures, safeguards, data practices and management, collaborative working, publication and authorship, as well as reviewing and assessment.

- **The General Data Protection Regulation (GDPR)** (Regulation (EU) 2016/679): The GDPR governs the processing of personal data in the EU mainly, requiring a lawful basis, data subject rights, Data Protection Impact Assessments (DPIAs), where there is high risk, rules for international transfers, and the principles of accountability, data minimisation, security, and transparency.

Additionally, in the task corresponding to this deliverable, ethics guidelines and EU regulations related to Artificial Intelligence (AI), such as the Ethics Guidelines for Trustworthy AI and the EU AI Act, will also be considered.

- **Ethics Guidelines for Trustworthy AI** (presented on 8 April 2019 by the European Commission's High-Level Expert Group on AI, AI HLEG): According to these guidelines, trustworthy AI should be lawful, ethical and robust. They list 4 principles for trustworthy AI: respect for human autonomy, prevention of harm, fairness, and explainability. They also propose 7 key requirements that AI systems must meet to be considered trustworthy: human agency and oversight, technical robustness and safety, privacy and data governance/protection, transparency and explainability, diversity, non-discrimination and fairness, accountability, and societal and environmental well-being.
- **EU AI Act** (Regulation (EU) 2024/1689): Regulation for the placing on the market, putting into service, and use of AI systems in the Union. It is based on the classification of AI systems according to their risk (risk-based approach):
 - Unacceptable risk: Prohibited (e.g., social scoring).
 - High risk: AI use cases that can pose serious risks to health, safety or fundamental rights.
 - Limited risk: Associated with a need for transparency around the use of AI.
 - Minimal risk: This AI has no additional regulatory obligations under the AI Act.

The AI Act establishes obligations based on the role, the classification of the AI system, and the categorization of the AI model (general-purpose AI or general-purpose AI with systemic risk).

Throughout the document (Chapter 7), the guidelines and regulations related to AI are explained in greater detail.

In addition to the above, all partners are required to comply with the applicable national legislation in their respective countries, particularly concerning data protection and ethics.

5 ETHICS COMMITTEE/GROUP

This chapter outlines the responsibilities, structure, and roles of Ethics Committee, which is responsible for carrying out Task 8.3 ("Ethical Dimension Management").

5.1 MISSION

The mission of the Ethics Committee/Group is to ensure that all project activities are conducted in compliance with ethical and regulatory principles, as well as data protection and privacy requirements, covering all phases of the MODALSHIFT project from start to finish.

In particular, it will be responsible for coordinating, supervising, managing, and addressing the ethical aspects of the project, in accordance with the ethical and regulatory framework described in Section 4.1, providing advice and/or training when necessary. This work will be carried out systematically and continuously throughout the entire project, covering the ethical aspects related to the development, implementation, and use of the planned technologies and activities.

All project partners or team members are required to communicate to the Ethics Committee/Group any ethical aspects addressed in their activities.

5.2 STRUCTURE AND ROLES

The Ethics Committee/Group has been established to ensure representation of all relevant parties involved in the project, ensuring compliance with ethical and regulatory requirements across all activities throughout the project. It is a transversal group responsible for the completion of all ethical and transparency obligations of the Horizon MODALSHIFT project.

Table 2 shows the key members who make up the committee, as well as their specific responsibilities, as defined and agreed upon in prior meetings. This composition reflects the current/initial status and may be updated throughout the project as needed.

Table 2: Ethics Committee/Group

	Partner	Responsibilities
Leader of WP8 and Task 8.3 (<i>"Ethical dimension management"</i>) Leader of Task 2.1 (<i>"Data management and governance"</i>)	ITA	*Acting as the central communication hub within the Ethics Committee and Ethics Strategy (Task 8.3). * Coordination and management of the Ethics Committee and Task 8.3, overseeing all ethical aspects of the project and coordinating related activities such as workshops, training sessions, and ethical awareness actions. *Assessing, monitoring, and ensuring best practices for compliance with the EU AI Act for services using AI, if applicable. *Responsible for DMP.
Leader of Task 2.3 (<i>"Data anonymisation and augmentation processes for data privacy and security"</i>)	OCTO	*GDPR and anonymization expert. *Deliver 2 workshops on training on data anonymization
Assigned representatives: One representative per system/service or WP leader	All	*Centralize and provide the required information regarding their systems. Communicate all relevant ethical aspects to their team that concern them. *Inform the Ethics Committee of any ethical aspects addressed in their activities, as well as any changes in the definition or development of the systems that may affect AI or ethical aspects. *Comply with the applicable legislation in their respective countries.
Other partners with related tasks within the Ethical Plan framework	UTAC (Leader of Task 2.5)	*Cybersecurity guidelines and tests

5.3 DELIVERABLES RELATED

Taking into account the objective of this plan and the ethical and regulatory framework on which the MODALSHIFT project is based, as described in Section 4.1, this deliverable is closely linked to other project deliverables that also address aspects related to ethics, integrity, and regulatory compliance.

Table 3 presents the main related deliverables, with which it maintains a direct connection. The Ethics Committee will be actively engaged in these deliverables through review, monitoring, direct participation, or by being kept informed of their progress and updates. The ethical, regulatory and management aspects will be addressed and explained in detail in their respective documents/deliverables.

Accordingly, this deliverable (D8.2) focuses primarily on aspects such as alignment with the EU AI Act, as well as on providing guidance and centralising ethical considerations (Section 4.1). Other related ethical issues are discussed in detail in the corresponding deliverables; for example, data management and privacy aspects are addressed in Deliverable 2.1 (DMP).

Table 3: Deliverables related

Deliverable	Leader	Ethical relation	EU AI Act relation
<i>D2.1: Data Management Plan</i>	ITA	DMP describes how data is managed and protected, providing evidence of compliance with the GDPR and aspects related to the EU AI Act.	Art. 10 – Data and data governance Art. 12 – Record-keeping Art. 11 – Technical documentation (Annex IV)
<i>D2.3: Processes for data anonymisation and treatment</i>	OCTO	GDPR principles and compliance.	Art. 10 – Data and data governance Art. 11 – Technical documentation (Annex IV)

Furthermore, the Ethics Committee must be kept informed of other deliverables and review them, when necessary, whenever they address aspects related to ethical considerations (see Section 4.1).

5.4 TRAINING PLAN

As part of the ethics group's activities, workshops will be conducted to build capacity, raise awareness within the consortium, and communicate relevant information on key ethical concepts, their importance, and the related procedures. Specifically, these sessions will focus on providing AI best practices, and the essential foundations to ensure ethical compliance and effective communication of information throughout the project.

Procedure for organizing workshops or capacity-building activities

Before launching a workshop or activity, the following procedure will be followed.

Responsible: Ethics Committee/Group Leader (ITA)

- 1) Identification of activities: Identify workshops or activities to be conducted based on project needs.
- 2) Assignment of responsible partners: Identify and communicate the people or partners responsible or involved in each activity.
- 3) Content review and validation: Schedule a meeting with responsible to review the scope and validate the workshop or activity content.
- 4) Scheduling: Send invitations to set the workshop date within a range of options.
- 5) Materials: Ensure that all necessary materials or documentation are available for the consortium.

In particular, two workshops have been defined so far, which will be conducted with the aim of ensuring that all technical partners are fully aligned with the project's AI strategy, are aware of, and adopt the most recent AI best practices. Specifically, these workshops will cover a comprehensive training on data anonymization, including: understanding personal data and associated risks; an overview of the GDPR, its origins, key principles, and legal bases for secondary data use; and a detailed explanation of the criteria that define when a dataset can be considered anonymous, following regulatory guidance from the European Data Protection Board (EDPB) — specifically addressing description of three criteria: *singling-out*, *correlation*, and *inference*. The sessions will also include a demonstration of the Avatar anonymisation solution, provided by the partner OCTO, and an open discussion on how anonymisation can be effectively applied within the MODALSHIFT context.

Additionally, if needed, tailored support workshops for specific use cases (practical workshops) may be organized.

These workshops address responsible AI best practices, with a particular focus on the third ethical principle concerning data privacy and governance. Additionally, these activities may also relate to the principle of transparency by promoting clear communication and understanding of ethical and technical procedures.

The following sections present general information about each of the defined workshops.

5.4.1 WORKSHOP 1

Title: Legal principles behind anonymisation

Responsible partner: Octopize

Estimated duration: 1.5-2 hours (may be repeated twice for time suitability)

Date: 4th December 2025

Aim: To raise awareness in the consortium regarding data anonymisation and its ethical and legal implications.

Description: The session will cover the key legal principles underpinning anonymisation, including a practical demonstration of the Avatar method. It will address the scope of application (types of data and criteria for anonymisation) and include an interactive discussion on applying anonymisation techniques in the MODALSHIFT project.

The workshop will be recorded for later viewing if attendance is not possible.

5.4.2 WORKSHOP 2

Title: Anonymisation with avatars in the MODALSHIFT context

Responsible partner: Octopize

Estimated duration: 1.5-2 hours (may be repeated twice for time suitability)

Tentative date: June 2026

Aim: To enable partners to run an anonymisation (with the support of Octopize)

Description: The session will be more technical, focusing on data preparation and accepted schemas, complemented by tutorials for different usages (e.g., tabular and geolocation). It will be scheduled after the completion of D1.1 (Plan for engaging stakeholders), D1.2 (Use cases and strategies for social optimum), and D1.3 (Technical specifications, including system functional architecture) to ensure alignment with MODALSHIFT requirements.

5.5 ACTIONS TAKEN

This section aims to list the actions and meetings carried out by the members of ethics committee since September (first version, to be updated):

- Ethics Group Meeting [16 September 2025]: Roles and responsibilities, the general methodology, and related to the EU AI Act were presented, along with the tentative workshops. A meeting summary was circulated, and the PowerPoint presentation was shared.
- Deliverable D.2.1 (DMP) [26 September 2025]: The DMP was defined, and ethical aspects such as privacy and data management were addressed.
- Meeting with OCTO and ITA regarding workshops [15 October 2025]: Workshops related to data anonymization were planned and their content validated, including proposed dates.
- First Workshop (1st Ethical Workshop on Data Anonymization) scheduled: 4 December 2025.
- Development of Task 3.2 (Deliverable 8.2, first version):
 - Assessment of ethical risks and definition of ethical requirements.
 - Proposed evaluation strategy on AI development, in accordance with the AI Act.

6 ETHICAL REQUIREMENTS

The aim of this chapter is to define the project's ethical requirements in line with EU standards. It establishes the operational framework that turns principles into verifiable conditions and safeguards across all activities, ensuring ethical compliance, data protection, legal safeguards, and participant safety.

Process:

1. **Ethics Self-Assessment (ESA):** Conducted at the proposal phase as an initial ethics and privacy assessment to identify ethical risks and compliance commitments.
2. **Ethics Risk Assessment (ERA):** Systematic evaluation of each identified risk (impact × likelihood) and definition of mitigation actions and acceptance criteria.
3. **Ethical Requirements:** Set of mandatory conditions and safeguards (e.g., informed consent, data minimisation/anonymisation, access controls, traceability, etc.) that must be met to ensure compliance with the EU AI Act, the GDPR, and European ethical principles.
4. **Implementation and evidence:** Application of measures and continuous monitoring.

This framework follows a continuous cycle of Identification → Assessment → Mitigation → Monitoring → Review, ensuring continuous improvement and the traceability of ethical decisions.

This is the first version of the process and reflects the initial considerations. Throughout the project, the framework will be reviewed iteratively to adapt to new activities, considerations, changes in systems or technologies, and new risks not initially contemplated, updating the Ethical Requirements and their mitigations as appropriate.

6.1 ETHICS SELF-ASSESSMENT

MODALSHIFT has undergone an initial ethics and privacy assessment during the proposal phase. Based on the outcomes of the *Ethics Self-Assessment* and the internal Ethics Committee setup, the project has received preliminary clearance to proceed with activities involving data collection, processing, and stakeholder participation, under the condition that all applicable ethical safeguards are implemented throughout the project duration.

Table 4: Overview of Ethics Requirements and Identified Issues in MODALSHIFT

Ethics Section	Identified Issues
----------------	-------------------

Section 2 – Humans (H)	Engagement of citizens and stakeholders in surveys, interviews, and co-creation events
Section 4 – Personal Data (POPD)	Processing of mobility-related personal data (e.g., GPS logs, BLE tracking, user surveys)
Section 6 – Non-EU Countries (NEC)	Collaboration or data flows involving technical platforms hosted in non-EU territories
Section 8 – Artificial Intelligence	Use of AI algorithms in digital twins and behavioural prediction models involving sensitive datasets

MODALSHIFT commits to monitoring and updating its ethics compliance measures in line with this guidance. The Ethics Committee will lead this process, ensuring that relevant safeguards, policies, and corrective actions are implemented and reviewed regularly. Focus will be placed on the following areas:

- Ensuring that informed consent is obtained and documented for all human participation (e.g., surveys).
- Maintaining GDPR compliance and robust data anonymization methods in all pilot cases involving personal data.
- Evaluating the use of AI algorithms for fairness, bias mitigation, and transparency.
- Managing any data transfers involving non-EU territories in accordance with European data protection regulations (e.g., adequacy of decisions).

The Ethics Committee will provide periodic updates and formal reports as required, especially in coordination with future versions of the deliverables related (Section 5.3) and the outcomes of pilot deployment activities.

6.2 ETHICS RISK ASSESSMENT AND REQUIREMENTS

The four ethics-related issues identified in the MODALSHIFT Ethics Self-Assessment namely those pertaining to humans, personal data, non-EU data flows, and the use of AI are further addressed in the following sub-sections. This self-analysis follows the guidance outlined in the European Commission's Ethics Self-Assessment Guide and serves to clarify how MODALSHIFT ensures ethical compliance across its research and innovation activities (Annex A – Ethics Self-Assessment Summary and ethics requirements).

6.2.1 HUMANS

MODALSHIFT involves the participation of human subjects, primarily through:

- Voluntary engagement in non-medical studies such as interviews, co-creation workshops, surveys, and behavioural feedback activities.
- Participants will not include:
 - Healthy volunteers for medical/clinical studies.
 - Patients participating in health-related interventions.

Due to the nature of MODALSHIFT's pilot activities especially in the areas of urban mobility, accessibility, and digital incentive systems some potentially vulnerable individuals or groups may be involved, including elderly users, low-income individuals, or persons with mobility limitations. Participation from these groups is crucial to the co-design and validation of more inclusive mobility services.

H- Identification and recruitment procedures report

Participants in this project will be identified and recruited following transparent and ethically sound procedures. Recruitment will be conducted using non-coercive methods, such as public calls for participation, institutional networks, and professional referrals where appropriate. All inclusion and exclusion criteria will be clearly defined to ensure fairness and representativeness, while respecting the rights of vulnerable groups. Before participation, individuals will be fully informed about the objectives, procedures, potential risks, and benefits of the study.

Participation is strictly voluntary, and individuals may withdraw at any time without any negative consequences. Informed consent will be obtained in writing, with copies of the consent forms and information sheets provided to all participants.

Ethical safeguards, informed consent protocols and more information related are in place and described in more detail in Deliverable 2.1 and Annex B – Informed Consent Form Templates.

6.2.2 PERSONAL DATA

MODALSHIFT may involve the processing of personal data, including:

- GPS traces from mobile applications.
- Public transport card usage logs.
- Survey responses with optional demographic details.

However:

- MODALSHIFT does not process special categories of personal data, such as biometric, health, political, religious, or genetic information.
- The project does not conduct profiling, large-scale monitoring, or employ intrusive methods such as covert surveillance or automated decision-making.
- No further processing of previously collected personal data or merging external datasets is planned without ethical clearance.
- The project does not export personal data from the EU to non-EU countries.

That said, importing anonymized or aggregated personal data from outside the EU may occur. For example, sensor or app data collected locally in the Bulgarian or Italian pilots might be transferred to central EU-based analytics platforms for processing. MODALSHIFT does not process any personal data related to criminal records or offenses.

POPD – Processing of personal data report

All personal data in MODALSHIFT will be handled in accordance with the GDPR and relevant national frameworks. Data collection will be limited to what is necessary for the project objectives and, wherever possible, data will be anonymised or aggregated. For participant-facing activities (surveys, co-creation workshops, and the mobile app), processing will be based on explicit consent, which may be withdrawn at any time without consequences. Participants will be informed about the categories of data collected, the purposes of processing, the storage period, and their rights (access, rectification, erasure, withdrawal of consent, and the right to lodge a complaint with a Data Protection Authority). Data will be encrypted and stored securely on EU servers, shared only with project partners for research purposes, and will never be sold or used for commercial purposes. The project will not process special categories of personal data, will not conduct profiling, large-scale monitoring, covert surveillance, or automated decision-making, and will not process data on criminal convictions or offences. No exports of personal data outside the EU are foreseen. Import of anonymised or aggregated data from outside the EU may occur, and, where used, such data will be processed on secure EU infrastructure in accordance with GDPR and national law. No further processing of previously collected personal data or merging with external datasets will be undertaken without prior ethical clearance. Data will be retained only for the duration of the project and then deleted.

More details on this can be found in Deliverable 2.1.

6.2.3 NON-EU COUNTRIES

Some MODALSHIFT activities may involve data exchanges or institutional collaboration with non-EU countries, including partners operating infrastructure or analytical platforms. However, as of the first version of the plan, MODALSHIFT does not involve the transfer of personal data to non-EU countries, nor are there pilot sites located outside the EU.

Nevertheless, the project is aware of potential ethical and legal considerations for data transfers originating from outside the EU and imported into EU-based processing environments (e.g., if any aggregated datasets or survey results are hosted by subcontractors based in non-EU countries). These scenarios, if they arise, will be reviewed by the Ethics Committee and handled according to the following principles:

Canada has received adequacy decisions from the European Commission, allowing limited data transfer under GDPR-compliant conditions.

For non-adequate countries, Standard Contractual Clauses (SCCs) or other legal safeguards will be applied as necessary.

No low- or lower-middle-income countries are involved in MODALSHIFT, and there are no plans to import or export biological materials, genetic data, or culturally sensitive resources.

The current version of the DMP confirms that:

- MODALSHIFT activities in non-EU countries do not raise major ethical concerns.
- Any potential future data imports (e.g., open datasets or tools) will undergo ethics and legal screening.
- The data platform infrastructure is hosted entirely within the EU, ensuring GDPR-compliant storage and analysis.

NEC – Import/export with non-EU members report

Where relevant, MODALSHIFT may involve institutional exchanges with non-EU (third) country partners operating infrastructure or analytical platforms; however, at this stage no transfers of personal data from the EU to third countries are foreseen, no pilot sites are located outside the EU, and the data platform is hosted entirely within the EU. If any imports into the EU arise, they will undergo Ethics Committee and compliance review to confirm legal basis, data minimisation and appropriate safeguards, and will be formalised through Data Processing Agreements (DPAs) and/or Data Transfer Agreements (DTAs); processing will occur on EU-hosted infrastructure, and all decisions will be documented. Should future exports of personal data prove strictly necessary, transfers would rely only on GDPR-approved mechanisms, including adequacy decisions (e.g., Canada, where applicable) or Standard Contractual Clauses with supplementary measures as appropriate. MODALSHIFT does not involve low- or lower-middle-income countries and does not plan to import or export biological materials, genetic data, or culturally sensitive resources; accordingly, the Nagoya Protocol and MTAs are not applicable.

Further clarification and updates on cross-border data flows will be provided in the next DMP update (Deliverable 2.1), particularly if additional subcontractors or replication activities are added.

6.2.4 ARTIFICIAL INTELLIGENCE

MODALSHIFT leverages AI in several technical components, including predictive modelling, digital twin simulations, and behaviour analytics tools designed to support sustainable mobility and logistics. These AI systems are used in non-invasive, post-processed contexts where human oversight remains central. In accordance with the EU AI Act and the European Commission's High-Level Expert Group on AI guidelines, MODALSHIFT adopts a risk-aware and ethics-by-design approach. In terms of Artificial Intelligence, the use of observation tools (e.g., video-based traffic monitoring) requires adherence to the EU AI Act and applicable national data protection laws (such as Austria's Data Protection Act). Processing of sensitive imagery is restricted to authorised, confidential procedures with encryption and automated anonymisation (e.g., blurring of faces and personal identifiers). This ensures that individuals cannot be identified and that ethical standards such as fairness, human agency, and non-discrimination are maintained.

Key AI pilot cases include:

- Data-driven forecasting of traffic and modal shift patterns using historical and real-time data.
- Demand prediction for logistics and public transport services.
- Optimisation of routing and travel-time estimation algorithms.

- Agent-based simulation.

While these AI applications do not directly interact with users in real time, MODALSHIFT ensures the following safeguards:

- **Transparency:** All models, training data, and assumptions may be documented and made available for review.
- **Data Governance:** Where required and technically feasible, AI systems will use anonymised or pseudonymized datasets for training instead of identifiable personal data.
- **Oversight:** AI-generated outputs will always be reviewed by human experts before decision-making or publication.
- **Non-discrimination:** Training data will be audited to minimise biases, and inclusive mobility indicators will be monitored for fairness.
- **Accountability:** AI performance will be benchmarked and validated, with clear documentation of limitations, caveats, and expected outcomes.
- **Societal Benefit:** AI tools are designed to contribute to sustainable urban mobility and equitable access, supporting the broader goals of the European Green Deal and Sustainable Development Goals (SDGs).

The following chapter (Chapter 7), provides a detailed overview of the Ethics Strategy Plan for Responsible AI Development (Strategy on AI development), for compliance with the Ethics Guidelines for Trustworthy AI and the EU AI Act.

In addition to the points mentioned above, any additional requirements arising from future reviews, such as an EPQ – Health and Safety Procedures Report, will be addressed in later stages and updates if necessary.

Table 5 presents a summary of the Ethical Requirements Register in its initial version. It will be updated iteratively as new activities, technologies, or risks emerge, etc. For each ethical area, the scope, standard requirements, mitigation measures, responsible individuals, and status are detailed.

Table 5: Overview of Identified Ethics Topics and Mitigation Measures in MODALSHIFT (Ethical Requirements Register)

Code	Scope in MODALSHIFT	Standard Requirements	Mitigation measures	Responsible	Status
H (Humans)	Surveys, interviews, co-creation; may involve vulnerable groups; no clinical studies/patients	Written informed consent; right to withdraw; safeguards for vulnerable participants	Informed consent, voluntary participation	Pilot cities, WP Leads	In progress
POPD (Personal Data)	GPS app traces, public transport card logs, survey data	GDPR compliance; purpose limitation & minimisation; anonymisation/aggregation where possible;	GDPR compliance, secure storage	Data controllers	In progress
NEC (Non-EU Countries)	No pilot sites outside EU; no EU→non-EU personal-data transfers planned; possible imports of anonymised/aggregated data	Legal basis (SCCs/adequacy); Transfer Impact Assessment; agreements (DTA/MTA); equivalent safeguards.	Based on GDPR Art. local laws	Coordinator, Legal team	In progress

Others	AI services	Compliance with EU AI Act (risk management, data and governance, technical documentation, record-keeping, transparency...)	Compliance with EU AI Act principles	Tech providers (support from Ethical Committee)	To be evaluated

The matrix below (Table 6) is a sample template for the Ethical Risk Assessment (ERA) and supports continuous monitoring throughout the project. It will be updated as the project progresses or as AI systems evolve.

Table 6: Example template for ERA

Ethics Area	Description of Risk	Likelihood (1–5)	Impact (1–5)	Risk Level	Mitigation / Control Measures	Responsible	Evidence / Deliverable
Human participants	Participants not fully informed about research aims or data use.	1	5	High	Standardized consent forms		
Personal data (POPD)	Risk of re-identification after data sharing.	1	5	High	Anonymisation/GDPR		

7 STRATEGY ON AI DEVELOPMENT

This chapter establishes the general strategy to be followed for AI-enabled services or developments within the project MODALSHIFT, with the aim of assessing and ensuring their alignment with the principles of the EU AI Act and the ethical principles for trustworthy AI presented by AI HLEG.

7.1 ETHICAL PRINCIPLES. TRUSTWORTHY AI

Our strategy is built upon the Ethics Guidelines for Trustworthy AI as outlined by the European Commission's High-Level Expert Group on AI and the ethical requirements of the Horizon Europe programme. According to these guidelines, trustworthy AI should be lawful, ethical and robust. There are seven key requirements that must be met:

- **Human agency and oversight:** AI systems will be designed to empower human beings, allowing for meaningful human oversight. Final decision-making authority on critical matters will remain with humans. Three approaches used: human-in-the-loop, human-on-the-loop and human-in-command.

- **Technical robustness and safety:** AI systems must be resilient against misuse or malfunction, secure, accurate, reliable and reproducible. In case of failure, a fallback plan must be used. The implementation of rigorous testing protocols can be used to prevent and mitigate unintended harm.
- **Privacy and data governance/protection:** The highest standards of privacy and data protection, adhering strictly to GDPR will be ensured. Data processing will be lawful, fair, transparent, and limited to its intended purpose (purpose limitation and data minimization).
- **Transparency and explainability:** Transparency regarding the data, algorithms, and models used will be maintained. Where appropriate and feasible, explanations for the decisions made by our AI systems (explainability) must be provided.
- **Diversity, non-discrimination and fairness:** An active work must be done to identify and mitigate unfair bias in the datasets and algorithms to ensure fairness and prevent discrimination or bias against any individual or group. The outcomes must be equitable.
- **Accountability:** Responsibility and accountability mechanisms for AI systems and their outcomes should be implemented. Auditability, which enables the assessment of algorithms, data and design processes. It is important to ensure accessible redress.
- **Societal and environmental well-being:** Minimize environmental and social impacts. The project will strive to produce a positive impact on society and the environment, considering its long-term consequences.

The AI HLEG provides a checklist for trustworthy AI (Assessment List for Trustworthy AI - ALTAI), in which AI principles are translated into a practical, accessible, and dynamic guide that directs developers and users in their application. This tool is intended to be used within the methodology to evaluate the AI of the services developed within the project.

7.2 EU AI ACT

The AI Act (Regulation (EU) 2024/1689 laying down harmonised rules on artificial intelligence) is the first-ever comprehensive legal framework on AI worldwide. It is the regulation for the placing on the market, putting into service, and use of AI systems in the Union. It is based on the classification of AI systems according to their risk (risk-based approach):

- **Unacceptable risk:** Prohibited (e.g., social scoring).
- **High risk:** AI use cases that can pose serious risks to health, safety or fundamental rights (for example, AI safety components in critical infrastructures (e.g. transport), the failure of which could put the life and health of citizens at risk).
- **Limited risk:** Associated with a need for transparency around the use of AI (e.g. chatbots or deepfakes).
- **Minimal risk:** Basic AI functionalities, such as some AI enabled video games or spam filters. This AI has no additional regulatory obligations under the AI Act.

The AI Act establishes obligations based on the role, the classification of the AI system, and the categorization of the AI model (general-purpose AI or general-purpose AI with systemic risk).

Except for the systems listed in Art. 5, all other AI systems within the scope of the AI Act (Art. 2) are considered permitted, but subject to certain obligations, except those categorized as minimal risk, which have no associated obligations.

Limited-risk systems, in turn, are subject to information and transparency requirements. The AI Act introduces specific disclosure obligations to ensure that humans are informed when necessary to preserve trust. High-risk AI systems (Art. 6, Annex III) are also subject to compliance with AI requirements and ex-ante conformity assessments before they can be put on the market. These obligations or requirements include:

- adequate risk assessment and mitigation systems (Art. 9 – Risk management system).
- high-quality of the datasets feeding the system to minimise risks of discriminatory outcomes (Art. 10 – Data & data governance).
- logging of activity to ensure traceability of results (Art. 12 – Record-keeping, Art. 19 – Automatically generated logs).
- detailed documentation providing all information necessary on the system and its purpose for authorities to assess its compliance (Art. 11 – Technical documentation, Annex IV)
- clear and adequate information to the deployer (Art. 13 - Transparency and Provision of Information to Deployers)
- appropriate human oversight measures (Art. 14 – Human oversight)
- high level of robustness, cybersecurity and accuracy (Art. 15 – Accuracy, robustness and cybersecurity).

Many of these aspects are linked to the tasks carried out by members of the ethics group in other activities and deliverables.

The AI Act came into force on 1 August 2024 and is expected to be fully applicable within the next two years, with some exceptions. The prohibitions and obligations related to AI literacy came into effect on 2 February 2025, while the governance rules and requirements for GPAI models became applicable on 2 August 2025. Meanwhile, the provisions concerning high-risk AI systems integrated into regulated products have an extended transition period.

The development of the project falls within the initial phase of regulatory implementation, making it important to consider and follow an evaluation system and best practices in accordance with the AI Act for possible future developments and implementations. To assess the level of compliance and potential obligations, a specific methodology is established within the project, when applicable, as part of the tasks of the ethics group.

7.3 METHODOLOGY

This section describes, at a high level the methodology for reviewing and assessing alignment with the EU AI Act and identifying applicable obligations. It applies to all AI-based services within the project and is integrated with the Ethical Risk Assessment (ERA) and the Ethical Requirements Register.

When it is intended to be evaluated:

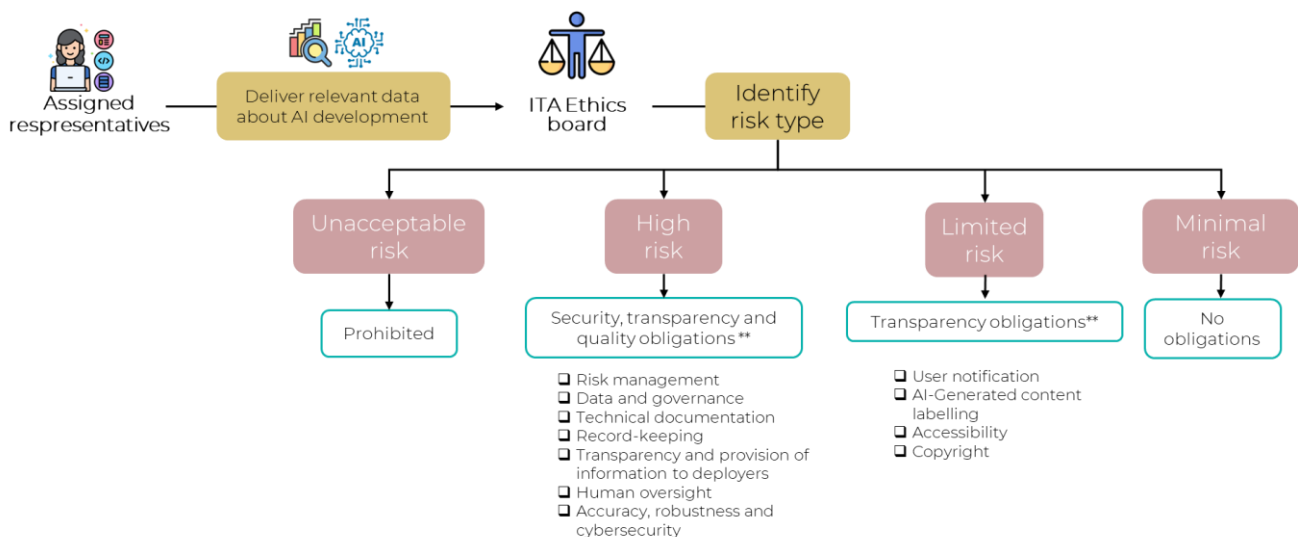
- Pilot design (at the start): Once the purpose, data, architecture, actors, and all considerations related to the AI system are defined and/or begin to be implemented or developed.
- Upon substantive changes: When there are changes related to the initially defined definitions and requirements, such as a new model or data version, a change of purpose, etc. Any modification to the system or new AI service must be communicated to carry out the assessment.
- At the end: Final verification.

7.3.1 GENERAL PROCEDURE

The proposed general evaluation procedure (Figure 1) is as follows:

1. **Identification and registration of AI systems:** Inventory of AI services and an information sheet for each, including purpose, tasks, data (sources and types), third-party dependencies (APIs), infrastructure, geographic scope, etc. A pre-check is conducted using a checklist and a brief survey; if details are missing, additional information is requested, or a meeting is scheduled with the responsible person.

2. **Trustworthiness self-assessment (ALTAI):** Application of the Assessment List for Trustworthy AI (ALTAI) as a practical guide. If gaps are identified, best practices and remediation measures are defined (e.g., improvements in transparency, explainability, fairness, security).
3. **Determination of scope under the AI Act:** Verification that the service fits the definition of “AI system” (Art. 2) and review of exclusions (e.g., R&D not introduced to the market/service). Even if excluded, the process will be evaluated when relevant, and best practices could be applied to facilitate future developments and early compliance.
4. **Role determination (Art. 3):** Identification of the applicable role: provider, deployer/implementer, distributor, or importer.
5. **Risk classification:** Classification of the system (prohibited / high risk / limited risk / minimal risk) and documentation of the rationale and resulting obligations.
6. **Mapping of obligations and controls:** May include risk management, data governance, technical documentation, logging and traceability, transparency and user instructions, human oversight, robustness, cybersecurity, and accuracy; additionally, non-discrimination and explainability proportional to risk. Best practices will be followed when applicable, generating recommended documents to comply with obligations, such as: risk management plan, dataset datasheet, model card, metrics evaluation, human oversight plan, incident management procedure, or logging plan, among others.



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Figure 1: General MODALSHIFT AI Act evaluation procedure

The persons responsible for the AI systems, with the support of the ethics team, must continuously monitor and review these systems in accordance with the points established in the methodology. In particular, ITA will be responsible for supervising and guiding the implementation of this evaluation plan or methodology. The members of the ethics committee assigned to each service or WP will be in charge of communicating and providing the necessary information. If necessary, meetings will be organized to address technical aspects in greater detail. Deliverables that include AI-related topics may be reviewed by the committee before publication in order to validate and take these aspects into account.

This constitutes the initial definition and framework, and may be modified along the project, if applicable. The Deliverable D2.1, in its Annexes, describes some of the technical guidelines applied to the use of AI systems and devices within the MODALSHIFT project.

8 CONCLUSION

This **first version** of the MODALSHIFT Ethical Strategy Plan (D.8.2) establishes the project's ethics backbone—governance, scope, and practical tools—to steer lawful, transparent, and risk-aware execution across the three case studies. It sets up the Ethics Committee/Group with defined roles and links to related deliverables, clarifies the ethical and legal foundations (Horizon Europe principles, GDPR, Trustworthy AI guidelines, and the EU AI Act), and frames ethics as a continuous, project-wide process. The initial focus converges on four areas—Humans, Personal Data, Non-EU Countries, and Artificial Intelligence—together with early guardrails such as EU-hosted processing, no foreseen exports of personal data outside the EU, and authorised, anonymised handling for any potentially sensitive observation data. Training and operational preparation have begun, with the first anonymisation workshop scheduled and a second, more technical session planned to deepen practical capabilities.

In the **next stages**, this living framework will be progressively operationalised: the Ethical Requirements Register and ethics risk assessments per activity/system will be completed and maintained, if applicable; consent and privacy artefacts will be finalised and embedded in practice; and AI systems will follow the project methodology—inventory, ALTAI self-assessment, scope and role determination under the AI Act, risk classification, and mapping of obligations with proportional controls (e.g., documentation, logging, human oversight, robustness, and non-discrimination). Cross-border checks will remain a standing item, with any non-EU imports screened and documented, and updates aligned with the DMP. Workshops will be delivered and iterated to consolidate shared competence, and AI-related deliverables may undergo pre-publication ethics checks to ensure consistency.

For **decision-making**, the Ethical Requirements Register should function as the single source of truth and gatekeeper before data collection, pilot deployments, or AI updates; unresolved issues should be escalated to the Ethics Committee/Group and recorded alongside evidence and mitigations. Given the project's iterative nature (M6–M42), periodic reviews will ensure proportionality, transparency, and continuous improvement, allowing MODALSHIFT to move confidently from principles to practice while protecting rights, fostering trust, and maximising societal benefit in sustainable mobility.

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10 ANNEX(ES)

10.1.1 ANNEX A – ETHICS SELF-ASSESSMENT SUMMARY AND ETHICS REQUIREMENTS

This annex provides an overview of the ethics self-assessment carried out within the MODALSHIFT project. It outlines key ethics issues identified during the planning and early implementation stages and summarizes the compliance measures put in place in line with applicable legal and ethical standards.

1. Ethics Issues Identified

The ethics review and self-assessment process identified the following key issues relevant to the project:

- Use of Human Participants.
- Volunteers may participate in surveys, interviews, or co-creation workshops. In some cases, vulnerable individuals such as children, elderly people, or people with reduced mobility may be involved.
- Personal Data Collection and Processing.
- Data collection activities involve personal data such as names, email addresses, location data, and mobility behavior. All processing activities must be submitted with the General Data Protection Regulation (GDPR)
- Non-EU Data Transfers.
- Project activities involve collaboration with partners in countries outside the EU (e.g., Canada). All data transfers to and from these regions are conducted under GDPR and respective national laws.
- Use of Artificial Intelligence.
- AI-based tools may be used on some pilot sites. These must comply with the EU AI Act and relevant principles on transparency, fairness, and data minimization.

2. Compliance Measures and Instruments

To address the issues above, the following measures are being implemented:

- Informed Consent Procedures.
- All participants are informed of their rights and the purpose of the data collected. Consent is collected prior to participation through digital or physical consent forms tailored to each data collection method and target group.
- Data Minimization and Anonymization.
- Only data strictly necessary for the research are collected. Personal identifiers are removed or pseudonymized where possible. Storage is secure using encryption protocols.
- Ethics Protocol Oversight.
- Project partners are required to ensure that research involving human subjects is approved by their respective institutional or national ethics committees where applicable. An internal ethics contact point is available to consult on open questions.
- Use of Digital Platforms.
- Tools used for data collection (e.g., surveys, tracking applications) are reviewed for data protection compliance. Participants are notified through signage, QR codes, and information sheets.

This ethics self-assessment will be updated as the project evolves, and additional data collection activities are launched. The project remains committed to ensuring the highest ethical standards in all its research activities.

10.1.2 ANNEX B – INFORMED CONSENT FORM TEMPLATES

This annex includes standardized templates for informed consent, designed to be adapted and used by all MODALSHIFT project partners engaged in collecting data from human participants. These templates reflect legal and ethical obligations under the General Data Protection Regulation (GDPR) and best practices in responsible research.

Templates cover the three main participant interaction types in the project:

C.1. Consent Form for Survey Participation

- Title of Study: [Insert specific activity or survey title]
- Responsible Institution: [Insert Partner Name]
- Contact Person: [Insert Name, Email]
- Purpose of the Study:

You are invited to participate in a survey related to mobility behavior. The goal is to collect insights that help design better and more solutions.

Voluntary Participation:

Participation in this study is entirely voluntary. You may decline to answer any question and withdraw at any point without any negative consequence.

Data Collection and Use:

Your responses will be used for research and statistical purposes only. Any data will be anonymized prior to being used for any communication or publication.

Confidentiality and Data Protection:

Data will be handled according to EU GDPR standards. Only authorized personnel will access your data, which will be stored securely.

Contact for Questions:

For questions or complaints about the study or your rights as a participant, contact: [Insert contact info]

Consent Statement:

- ☐ I confirm that I have read and understood the information provided.
- ☐ I voluntarily agree to participate in this survey

Signature: _____ Date: _____

C.2. Consent Form for Workshop Participation

- Title of Workshop: [Insert name of workshop]
- Facilitator/Partner: [Insert name]

Purpose of the Workshop:

This workshop invites participants to provide feedback and ideas for improving solutions.

Participation Details:

Participation is voluntary and any comments shared may be recorded (audio/video/text). Your input will help shape the project's mobility actions

Data Handling:

Video/images used for dissemination purposes will require additional media consent. for managing consent and compliance related to media content lies with the individual partners producing or disseminating the material, in line with GDPR and project ethics protocols.

Confidentiality and Data Protection:

Your information will be securely stored and used only for the intended research purposes in accordance with GDPR.

Consent Statement:

- ☐ I agree to participate in this workshop and understand my rights regarding data privacy.
- ☐ I give permission for anonymized quotes or insights I provide to be used in project reporting.

Signature: _____ Date: _____

C.3. Consent Form for Use of Mobile App:

- App Name: [Insert application name]
- Controller: [Insert organization operating the app]

Purpose of the App:

This app collects travel behavior data to analyze patterns and support sustainable mobility planning. The collected data is later anonymized through secure backend processing (not directly on the user's device).

Type of Data Collected:

The app collects location data (GPS), timestamps, and usage frequency. No data is shared with third parties.

Your Rights:

You may uninstall the app and stop participating at any time. Data already collected will either be deleted or retained in an anonymized way for project purposes only

Data Storage:

Data is encrypted and stored on secure servers under GDPR compliance.

Consent Statement:

☐ I understand how my data will be used and give me consent to use the app for this study.

☐ I agree to share mobility data with the project for research use only.

Signature (if applicable): _____ Date: _____

These templates are to be adapted by each MODALSHIFT partner to reflect local language requirements and data collection specifics. Translations and culturally appropriate adaptations must also respect inclusive language and ethical standards.