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D4.4 - ETHICS GUIDELINES ON RESPONSIBLE RESEARCH V1

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1.0	30/03/2025	Mariana Carvajal Sojo Gemma Galdón Clavell	First draft
1.1	25/04/2025	Mariana Carvajal Sojo, Maite Del Amo	Inclusion of feedback from reviewers
1.2	30/04/2025	Mariana Carvajal Sojo, André Carriero	Final review

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LIST OF ABBREVIATIONS

AI	Artificial Intelligence
EU	European Union
EC	European Commission
GDPR	General Data Protection Regulation
ALTAI	Assessment List for Trustworthy Artificial Intelligence
DPIA	Data Protection Impact Assessment

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2 EXECUTIVE SUMMARY

This first version of the ACHILLES Ethics Guidelines sets out a foundational framework to support partners in identifying and addressing ethical considerations throughout the lifecycle of the Project. While legal and procedural matters will be covered in detail through other deliverables (such as D4.1), this document focuses on how ethical principles should inform everyday research practices, with particular attention to the pilot phase in WP7.

These guidelines are structured to support partners in identifying ethical risks and responsibilities in relation to data protection, informed consent, and the broader principles of responsible research. In doing so, they reflect the ethical framework of the European Commission, including expectations under Horizon 2020[1], the General Data Protection Regulation (GDPR)[2], and the AI Act[3].

The document includes specific guidance on how to ethically manage data, engage with human participants, and approach the use of artificial intelligence in ways that are transparent, fair, and respectful of fundamental rights. A dedicated section addresses pilot activities, recognising the particular ethical questions that might arise when research is tested in real-world environments. In doing so, D4.4 offers orientation and promotes informed decision-making throughout the life cycle of the Project. Finally, these guidelines include a brief section on ethical dissemination practices, ensuring that the project dissemination activities also respect privacy, dignity, and the integrity of the research.

The Ethics Guidelines v1 will be updated in Month 28 (M28) to reflect the evolution of the Project, feedback from partners, and any relevant changes in regulatory or ethical expectations. In the meantime, this version serves as a common reference to support ongoing dialogue, consistent standards, and ethical accountability across the consortium.

1 European Parliament and of the Council. REGULATION (EU) 2021/695 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 28 April 2021 establishing Horizon Europe – the Framework Programme for Research and Innovation, laying down its rules for participation and dissemination, and repealing Regulations (EU) No 1290/2013 and (EU) No 1291/2013, OJ L 170, 12.5.2021 § (28AD).

2 European Parliament and of the Council. Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation) (Text with EEA relevance), OJ L 119, 4.5.2016

3 European Parliament and of the Council. Regulation (EU) 2024/1689 of the European Parliament and of the Council of 13 June 2024 laying down harmonised rules on artificial intelligence and amending Regulations (EC) No 300/2008, (EU) No 167/2013, (EU) No 168/2013, (EU) 2018/858, (EU) 2018/1139 and (EU) 2019/2144 and Directives 2014/90/EU, (EU) 2016/797 and (EU) 2020/1828 (Artificial Intelligence Act) (Text with EEA relevance), OJ L, 2024/1689, 12.7.2024

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3 INTRODUCTION

ACHILLES is a European Union-funded project under the Horizon Europe framework[4]. It brings together a multidisciplinary consortium committed to advancing trustworthy and efficient AI development across diverse sectors. Through its iterative development cycle and integrated AI environment, the Project addresses the technical, regulatory, and ethical complexities associated with real-world AI deployment.

Within this framework, the D4.4 Ethics Guidelines v1 contribute to ACHILLES's commitment to responsible research and innovation by identifying key ethical concerns and offering structured guidance for addressing them. While legal requirements and compliance mechanisms are detailed in other project deliverables (such as D4.1), these guidelines provide a practical reference for embedding ethical awareness into the design and execution of project activities, including data collection, human involvement, and pilot implementation.

This document begins by outlining the ethical standards that guide the ACHILLES approach, in alignment with Horizon 2020 and Horizon Europe expectations. It then explores how these standards apply to data governance, consent procedures, and the protection of human participants. Particular attention is given to the pilot phase of the Project, where AI tools will be tested in applied contexts such as healthcare, content creation, pharmaceuticals, and ID verification. The guidelines highlight how partners can anticipate and mitigate ethical risks in these environments, with an emphasis on transparency, accountability, and participant safeguards. Finally, the document addresses ethical considerations in dissemination and communication activities.

This first version will be followed by a second iteration in Month 28 (M28), which will incorporate lessons learned from early implementation and respond to new ethical issues as they emerge.

4 European Parliament and of the Council. REGULATION (EU) 2021/695 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 28 April 2021 establishing Horizon Europe – the Framework Programme for Research and Innovation, laying down its rules for participation and dissemination, and repealing Regulations (EU) No 1290/2013 and (EU) No 1291/2013, OJ L 170, 12.5.2021

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4 HORIZON EUROPE ETHICAL REQUIREMENTS

ACHILLES operates within the formal ethical obligations established by the European Commission for Horizon Europe-funded research and innovation activities. In line with Regulation (EU) 2021/695, particularly Article 19 on ethical principles, all Horizon projects must comply with fundamental ethical standards as well as relevant national, Union, and international legislation. This framework explicitly includes the Charter of Fundamental Rights of the European Union and the European Convention on Human Rights and its supplementary protocols.

Horizon Europe reinforces these obligations, placing particular emphasis on key ethical principles such as proportionality, respect for human dignity and integrity, the right to privacy, the protection of personal data, non-discrimination, and the promotion of high standards of health protection. These obligations are not treated as formalities but constitute the foundation upon which all research and innovation activities are expected to be designed and implemented. Horizon Europe therefore expects consortia not only to ensure that their research is ethically sound at the outset, but also to reflect critically on the potential future uses and misuses of their technologies.

To operationalise these commitments, the European Commission requires applicants to complete a structured Ethics Self-Assessment. This self-assessment is a critical exercise through which consortia identify any aspects of their research that may raise ethical issues. It serves both as a reflection tool for applicants and as an accountability mechanism for the European Commission to ensure that ethical considerations are fully embedded from the earliest stages.

The Ethics Self-Assessment process requires consortia to systematically evaluate whether their Project involves any of the following sensitive areas:

- Research involving human participants,
- The collection, processing, or reuse of personal data, including special categories of data as defined in the GDPR,
- The development or deployment of Artificial Intelligence (AI) systems or other emerging digital technologies,
- Research conducted in or involving third countries where legal and ethical standards may differ from those of the EU,
- Activities with potential for misuse, dual-use, or negative societal impact.

For each flagged area, applicants must describe the measures they will take to mitigate ethical risks. This includes providing information about risk assessment procedures, data protection strategies, informed consent processes, and safeguards for vulnerable groups or sensitive contexts. Additionally, applicants must complete the Ethics Issues Table, a checklist that summarises all the ethical issues identified and points to the mitigation measures proposed.

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Importantly, ethical compliance under Horizon Europe is conceived as a continuous responsibility, not a one-time declaration. Projects must monitor the ethical implications of their activities throughout their lifecycle, adjusting measures as necessary if new risks arise or if project activities evolve. In certain cases, the European Commission may initiate ethics checks, audits, or reviews to verify ongoing compliance.

The European Commission's guidance document, How to Complete Your Ethics Self-Assessment (2021)[5], explicitly frames ethics as an integral and evolving part of responsible research and innovation. It emphasises that consortia must not only assess the direct impacts of their research but also its indirect effects, long-term implications, and potential unintended consequences.

Beyond Horizon Europe's internal framework, ethical obligations are reinforced through references to broader human rights instruments. The Charter of Fundamental Rights of the European Union protects rights such as privacy (Article 7), the protection of personal data (Article 8), and non-discrimination (Article 21). Similarly, the Declaration of Helsinki[6] and the Belmont Report[7] continue to provide ethical guidance for research involving human subjects, particularly regarding respect for persons, beneficence, justice, informed consent, and risk minimisation.

As further elaborated in Deliverable D4.1 Legal and Ethical Mapping, these rights are also codified in international and regional legal instruments that support and inform Horizon Europe's ethical requirements. Instruments such as the European Convention on Human Rights (ECHR), the International Covenant on Civil and Political Rights (ICCPR), and the International Covenant on Economic, Social and Cultural Rights (ICESCR) serve as binding legal sources that underpin key ethical principles, including autonomy, dignity, privacy, and equality. Together, they provide the legal scaffolding for interpreting and applying ethical principles.

It is important to note that Horizon Europe recognises that ethical concerns do not arise solely when research involves direct human participation. Research that collects or processes personal data, that affects individuals through algorithmic decisions, or that impacts how people are perceived, classified, or treated, can equally raise ethical issues. For projects like ACHILLES, operating at the crossroads of AI development, personal data processing, and real-world human interactions, ethical oversight must be embedded at every stage of design, development, validation, and deployment.

5 European Commission . “EU Grants How to Complete Your Ethics Self-Assessment,” July 13, 2021.

6 World Medical Association. “WMA Declaration of Helsinki – Ethical Principles for Medical Research Involving Human Participants.” Wma.net. WMA - the World Medical Association-WMA Declaration of Helsinki – Ethical Principles for Medical Research Involving Human Participants, December 13, 2024.

7 U.S. Department of Health and Human Services. “The Belmont Report.” U.S. Department of Health and Human Services, 1979.

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In this context, ACHILLES is fully aligned with the expectations of Horizon Europe. Ethical reflection and safeguards are not treated as secondary compliance items but as fundamental elements of the Project's architecture.

4.1 Relevance of Horizon Europe in ACHILLES

In line with Horizon Europe's ethical framework and the guidance provided by the European Commission, projects must adhere to well-established best practices that are adapted to the specific areas of research they address. ACHILLES, operating across several sensitive domains, must integrate these recommendations into its design and implementation.

When research activities involve human participants, the Commission underlines the absolute necessity of ensuring voluntary, informed, and explicit consent. Participants must be clearly informed about the purpose, methods, risks, and benefits of their involvement, as well as about their right to withdraw at any time without any negative consequences. Particular attention must be paid to vulnerable groups, ensuring that their participation is free from coercion and that additional protective measures are in place where needed. Research must minimise potential harm and maximise potential benefits, applying the principles of respect for persons, beneficence, and justice, as outlined in international ethical standards.

For research involving the collection, processing, or reuse of personal data, best practices are rooted in the strict application of the General Data Protection Regulation (GDPR). Data must be processed lawfully, fairly, and transparently, with clear purpose limitation and strict minimisation of the information collected. Where special categories of personal data are involved, such as health or biometric data, additional safeguards must be introduced, including obtaining explicit consent and implementing technical and organisational measures to prevent unauthorised access or misuse. Anonymisation or pseudonymisation techniques should be used wherever feasible, particularly when data is to be shared beyond the original research team.

In cases where research activities involve non-EU countries, the European Commission expects consortia to ensure that the same high ethical standards are respected abroad as would be required within the Union. This includes verifying that local laws and practices provide an equivalent level of protection for participants and data subjects. Where such equivalence cannot be guaranteed, additional mitigation measures must be applied, or, in certain cases, research activities must be reconsidered. Particular care must be taken when transferring personal data outside the EU, ensuring that transfers comply with the conditions laid out in Chapter V of the GDPR, including the use of adequacy decisions, standard contractual clauses, or other appropriate safeguards.

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The development and deployment of Artificial Intelligence within EU-funded research projects carry their own specific ethical expectations. Horizon Europe emphasises that AI systems must be designed to respect fundamental rights, including human dignity, privacy, and non-discrimination. Best practices call for the integration of human oversight mechanisms, the implementation of fairness and bias mitigation strategies, and the promotion of transparency and explainability in algorithmic decision-making. Projects are encouraged to align their AI development with the principles outlined in the Assessment List for Trustworthy Artificial Intelligence (ALTAI), ensuring that systems are robust, safe, and accountable throughout their lifecycle.

By embedding these best practices into all phases of the research cycle, from planning to implementation and dissemination, ACHILLES seeks to ensure that ethical considerations are not treated as procedural requirements but as essential elements of responsible, high-quality innovation.

Additionally, responsibility under Horizon Europe is distributed. All partners are expected to identify risks in their areas of work and to contribute to the mitigation of those risks. This includes ensuring that consent processes are meaningful where applicable, that data is handled and shared in a secure and respectful manner, and that technical decisions are grounded in ethical reasoning. It also includes recognising when tools or systems developed in ACHILLES could be misused in other contexts and building safeguards that reduce this risk.

ETICAS provides dedicated support for risk identification, informed consent processes, bias mitigation, and responsible dissemination. Ethical inputs are not limited to compliance checks but are integrated into how the system is being designed, validated, and explained to users.

4.2 Application of Horizon Europe in ACHILLES

In ACHILLES, the ethical requirements established by Horizon Europe are being applied through a combination of technical safeguards, internal procedures, and reflective dialogue across the consortium.

Within the system architecture, ethical principles are being translated into requirements that influence how different modules are developed and evaluated. In Task 5.1, concepts such as fairness, transparency, and accountability are being incorporated into system design, with the aim of making these principles traceable and measurable. These values will shape how decisions are logged, how explanations are made accessible, and how user feedback is integrated.

In Task 1.2, the detection and mitigation of bias are approached through both technical and ethical lenses. While statistical techniques are being developed to identify patterns of exclusion, these are guided by broader concerns around representation and fairness. Legal and ethical partners are working with technical teams to help define what constitutes meaningful fairness across different use cases and stakeholder groups.

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The ethical framework is also being applied in the pilots. Each use case raises specific concerns that must be addressed in context. In the healthcare and pharmaceutical pilots, attention is being given to the risk of over-reliance on AI recommendations, the use of health-related data, and the need for clear communication with end users. In the ID verification pilot, safeguards are being developed to reduce the risk of exclusion, misidentification or unfair treatment, particularly in relation to the use of biometric data. These risks include false positives or negatives, potential bias in facial recognition systems, and the heightened sensitivity of biometric information due to its permanence and identifiability. In the content creation pilot, the consortium is actively discussing how to manage issues of authorship, consent, and representational harm.

To support implementation across these areas, ACHILLES has set up a structure that includes both proactive guidance and continuous support. ETICAS, in coordination with WP1, WP4 and WP5, provides recommendations on informed consent, data governance, and pilot-level ethical risks. Internal ethics checkpoints will be conducted throughout WP6 and WP7 to help partners anticipate and respond to ethical challenges before systems are finalised or tested in the field. By applying Horizon Europe's ethical standards in this way, ACHILLES fosters an ecosystem where technology is not only innovative and efficient, but also safe, inclusive, and socially responsible.

Finally, in line with the Horizon Europe Grant Agreement obligations and to ensure ethical oversight throughout the lifecycle of the Project, the ACHILLES consortium will establish an Ethics Committee. Such a body supports internal ethical reflection, monitors compliance with legal and ethical standards, and provides guidance on emerging issues, especially those involving AI, human rights, and data protection.

5 GDPR REQUIREMENTS

This section draws on the legal analysis developed in Deliverable D4.1 Legal and Ethical Mapping, which provides the foundational interpretation of the GDPR and its relevance to ACHILLES. D4.1 clarifies the definitions and scope of personal and special categories of data, the responsibilities of controllers and processors, and the legal basis for data processing. Its insights serve as a legal baseline that supports the ethical recommendations outlined here, ensuring that ACHILLES aligns the pertinent regulation. The General Data Protection Regulation (GDPR)[8] is the main legal framework governing the processing of personal data in the European Union. It applies to any activity that involves collecting, storing, processing, or sharing information about identifiable individuals, regardless of whether that data is collected directly by the Project or reused from external sources. As a Regulation rather than a Directive, the GDPR has direct effect in all Member States, which means its provisions must be respected in all research activities funded by the EU, including those carried out under Horizon Europe.

8 European Parliament and of the Council. Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and

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The GDPR defines personal data broadly. According to Article 4(1), personal data is any information relating to an identified or identifiable natural person. This includes obvious identifiers such as names or national ID numbers, but also covers biometric data, location data, and online identifiers when they can be linked back to a person. Biometric data, health data, and data revealing racial or ethnic origin, political opinions, or other protected characteristics are considered special categories of personal data under Article 9. These special categories of data are, in principle, prohibited from being processed, unless certain conditions are met, such as the data subject giving explicit consent, in line with Article 9 of the GDPR. In particular, partners are encouraged to carefully consider the implications of the following principles when collecting or processing personal data within the scope of ACHILLES:

- **Lawfulness, fairness and transparency (Article 5 (1) a),** according to Article 5 (1) a: "personal data shall be processed lawfully, fairly and in a transparent manner in relation to the data subject ('lawfulness, fairness and transparency')." Therefore, partners must process personal data lawfully, fairly and in a transparent manner in relation to the data subjects who will take part in the pilots developed in WP7.
- **Purpose limitation (Article 5(1)(b)),** according to this Article, personal data shall additionally be collected for specified, explicit and legitimate purposes and not further processed in a manner that is incompatible with those purposes; further processing for archiving purposes in the public interest, scientific or historical research purposes or statistical purposes shall, in accordance with Article 89(1), not be considered to be incompatible with the initial purposes (' purpose limitation'). This principle compels partners to collect data only for clearly stated and justified purposes. Ethically, this ensures that data subjects retain a degree of control and understanding over how their data contributes to the Project.
- **Data minimisation (Article 5(1)(c) GDPR)** states that no data should be collected if they are not strictly necessary for the declared purposes of the processing. In other words, if the utility of a piece of data is unclear, it should not be collected. Evidently, this requires a contextual judgement that takes into consideration the purpose of the processing and the suitableness of data in order to achieve it.
- **Accuracy (article 5(1)(d) and 16)** is essential in AI development. Incorrect data can produce harmful outcomes, especially when automated systems are involved. Ethical research therefore demands continuous monitoring and correction of inaccurate or outdated data. All data subjects whose personal data is managed by the Project have the right to request that Project partners erase or rectify without delay erroneous data that relates to them. The consortium must take every reasonable step to update or remove data that is inaccurate or incomplete. This principle is connected to the right to rectification contained in Article 16 GDPR, which grants data subjects the right to demand the revision of personal data that is not

on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation) (Text with EEA relevance), OJ L 119, 4.5.2016

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accurate. The importance of this principle arises from the potential damage that can be caused to a data subject if inaccurate data is associated to them.

- **Storage limitation (Article 5(1)(e))** entails that all partners must delete personal data when they no longer need it and as it is said above, the concrete retention period/s to be established are not fixed by law. Therefore, it must be determined on a case-by-case basis in attention to the nature of the processing and its purposes. The retention period needs to be justified on the grounds of its utility. No data can be held if they do not serve the purposes for which they were collected in the first place.
- **Integrity and confidentiality (Article 5(1)(f))** require that data is securely protected from breaches or misuse. Beyond technical compliance, this principle reflects the ethical obligation to prevent harm to individuals whose data is entrusted to the Project. All partners must keep personal data safe, secure and protected by using appropriate technical and/or organisational measures.
- **Pseudonymisation and anonymisation of data** encourage partners to place appropriate safeguards on data. Those safeguards shall ensure that technical and organisational measures are in place, in particular in order to ensure respect for the principle of data minimisation. Those measures may include pseudonymisation provided that those purposes can be fulfilled in that manner.
- **Processing of special categories of data (Article 9)**, such as health information or biometric data, is in principle prohibited, unless under certain conditions, such as obtaining explicit consent and respecting heightened safeguards. This is particularly relevant in ACHILLES pilots, where vulnerable groups may be involved or where inferences may be drawn from seemingly neutral but special personal data.

5.1 Relevance of GDPR for ACHILLES

Applying the GDPR in ACHILLES begins with recognising where personal data is involved. In several work packages, partners rely on datasets that include biometric information, health data, or other identifiers linked to individuals. Even when these datasets were collected prior to the Project or are pseudonymised, the GDPR still applies if individuals can reasonably be identified by any party.

Each partner must evaluate their role in relation to the data they use or produce. If a partner determines the purpose and means of processing data, they are a data controller (article 4(7)). If they process data on behalf of another entity, they act as a data processor (article 4(8)). In some tasks, partners may be joint controllers (article 26), particularly when developing or testing shared modules or datasets[9].

9 In accordance with the General Data Protection Regulation found in https://eur-lex.europa.eu/eli/reg/2016/679/oj/eng

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The principle of data protection by design should guide all system development (article 25). This means identifying risks to privacy and rights at the earliest possible stage and embedding safeguards such as anonymisation, pseudonymisation, restricted access, audit trails, and data minimisation directly into the system's architecture. These obligations are both technical and ethical in nature.

Informed consent, as the legal basis for processing personal data, must be meaningful, especially in pilot settings. Participants should understand how their data will be used, what risks may be involved, and what rights they have, including the right to withdraw consent (article 7)[10]. The use of pre-existing datasets must also be examined carefully to ensure that the original consent covers their use in ACHILLES, or that an alternative lawful basis is documented. All partners must ensure that they have procedures in place for responding to data subject requests, such as the right to access, rectification, or erasure.

5.2 Application of GDPR in ACHILLES

In ACHILLES, data protection will be implemented at both the organisational and system level. While not all activities involve personal data, several work packages do rely on information that falls under the scope of the GDPR. These include biometric data in the ID verification pilot (T7.2), health-related data used in the clinical (T7.1) and pharmaceutical (T7.3) pilots, and potentially identifiable input used in content generation (T7.5).

In addition, data may be processed in upstream tasks such as T5.1 (on modular integration and trustworthiness), T1.2 (bias detection and mitigation), and T6.1 (human-in-the-loop design). Even if the individuals involved are not directly identifiable, these tasks will need to ensure that the principles of data minimisation, purpose limitation, and transparency are respected throughout.

To support compliance, partners involved in these activities will apply the GDPR by limiting the processing of personal data to only what is strictly necessary, applying pseudonymisation or anonymisation where appropriate, and clearly documenting their legal basis for processing[11]. In most cases, this basis will be either informed or even explicit consent or the performance of a task carried out in the public interest related to scientific research.

While this section outlines how GDPR principles will be applied from an ethical standpoint, a more detailed description of the types of data processed, the technical handling of data, and data flows across the consortium is provided in Deliverable D9.4 (Data Management Plan). That document

10 See the Declaration of Helsinki (2013) and the Belmont Report (1978) for the ethical foundations of informed consent. Both provide essential ethical guidelines for research involving human beings.

11 European Parliament and of the Council. Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation) (Text with EEA relevance), OJ L 119, 4.5.2016

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complements the ethical reflection presented here by offering a comprehensive view of how data is managed across the lifecycle of the Project, in line with the FAIR principles and the roles and responsibilities defined under the Grant Agreement. Furthermore, Deliverable D4.1 (Legal and Ethical Mapping) provides the legal underpinning for the approach taken, analysing how GDPR provisions intersect with broader ethical requirements and supporting the operationalisation of these principles across the Project.

In line with Article 25 of the GDPR, ACHILLES adopts a "data protection by design and by default" approach. This is not only a technical requirement but an ethical commitment to anticipate potential harms, incorporate safeguards from the outset, and uphold participant dignity at all stages of the Project. Article 32 further reinforces the obligation to secure personal data using appropriate technical and organisational measures, which must be proportional to the risks involved and tailored to the specific nature of each use case.

Finally, the GDPR also calls for a clear allocation of responsibilities between data controllers, who determine the purpose and means of processing, and data processors, who act on their behalf. In a collaborative project such as ACHILLES, it is essential that these roles are well defined and that each partner understands their obligations under the law.

Informed consent and Ethical Safeguards

In ACHILLES, informed consent is not merely a legal requirement, but a foundational principle that ensures individuals understand their role in the Project, the type of data being collected, and the implications of their participation. It serves as both a safeguard for participants and a demonstration of the consortium's commitment to research integrity. Consent must be freely given, specific, informed, and unambiguous. These elements require not only a written form, but a meaningful process of communication. Individuals should know why their data is being collected, how it will be used, who will have access to it, and what rights they have over it, which includes the right to withdraw at any time without consequence. This applies across all research activities, whether participation takes place through surveys, interviews, user testing, or real-world interactions with AI systems in pilot settings.

The ethical relevance of informed consent becomes particularly significant during pilot implementation. Participants may be exposed to AI systems that perform analyses, make predictions, or adapt in real time. In these contexts, it is essential to explain not only that data will be collected, but also what the systems are designed to do and what role participant input or feedback might play (GDPR, Art. 4(11), Recital 32). This is especially important when systems have an observational or interactive component, or when personal data feeds into algorithmic processes that could impact individuals indirectly.

Consent forms must clearly identify the data controller and include contact details for both the responsible institution and the designated Data Protection Officer. This ensures participants have a clear point of reference if they wish to revoke consent, raise concerns, or access their data. Where data

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processing is shared across institutions or tasks, this should be explained transparently. Ethical informed consent is not a one-off event. It may require renewal, clarification, or adaptation during the course of the Project, particularly if the purpose of processing changes, new data is introduced, or systems evolve. In these cases, participants must be notified, and where necessary, asked to provide renewed consent.

In cases where indirect data is collected, participants should be informed of this possibility in advance. Even when this information is technically anonymised or aggregated, ethical responsibility requires partners to consider how individuals may perceive this use and what impact it might have on their willingness to engage. Finally, documentation of consent must be consistent, securely stored, and accessible for internal monitoring. All partners must ensure that consent is obtained before any data collection takes place and that consent materials are reviewed regularly for clarity and relevance. This includes reviewing how forms are presented, how long records are retained, and whether they remain aligned with project needs and ethical expectations (GDPR, Art. 7(3).

6 AI ACT REQUIREMENTS

The Artificial Intelligence Act is the European Union's horizontal regulatory framework for the development, deployment, and use of artificial intelligence systems. It entered into force in 2024, becoming the first binding legislation of its kind globally. The Act includes core provisions which has direct implications for EU-funded research and innovation projects such as ACHILLES.

The AI Act adopts a risk-based approach, categorising AI systems into four tiers: unacceptable risk (prohibited), high risk, limited risk, and minimal risk. High-risk systems include those used in biometric identification and categorisation, critical infrastructure (e.g., transport and energy), education and vocational training (e.g., automated grading or admission), employment and worker management (e.g., CV screening tools), access to essential private and public services (e.g., credit scoring, welfare eligibility), law enforcement (e.g., predictive policing), migration, asylum and border control (e.g., risk assessments), and the administration of justice and democratic processes (e.g., legal decision support tools). These must comply with strict requirements related to documentation, transparency, human oversight, robustness, and risk mitigation before they can be deployed or placed on the market (see Chapter III, Section II AI Act). In addition to this risk-based framework, the AI Act introduces tailored provisions for General-Purpose AI (GPAI) models and systems, which may not fall under any single risk category but have wide-ranging impacts. GPAI models are subject to specific transparency, safety, and traceability obligations, especially when integrated into downstream applications, including those classified as high risk.

According to Article 2(8), the regulation does not apply to AI systems or models during their research, testing, or development phase, as long as they are not yet placed on the market or put into service. This provision provides researchers with the necessary space to innovate and experiment. However, for systems that may ultimately be classified as high-risk, the Act expects early integration of compliance

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considerations. This includes anticipating how the system will ensure fairness, non-discrimination, traceability, explainability, and accountability.

The Act also reinforces the need for human-centric design, meaning that AI systems should not undermine individual rights, autonomy, or democratic values. This principle is especially relevant for ACHILLES, which develops modular AI systems and tests them in use cases with clear human and societal impact, such as identity verification, healthcare, and content generation. These reflections should be built into each phase of the AI lifecycle, including model design, training, validation, deployment, and monitoring, particularly in WP5, WP6, and WP7.

In parallel to the regulatory text, the European Commission has developed supporting ethical tools and guidance. The Ethics Guidelines for Trustworthy AI, published by the High-Level Expert Group on AI, outline seven core ethical principles: human agency and oversight, technical robustness and safety, privacy and data governance, transparency, diversity and fairness, societal well-being, and accountability. These guidelines form the basis of the Assessment List for Trustworthy AI (ALTAI), a voluntary self-assessment tool designed to help organisations evaluate their systems against ethical benchmarks.

Although ALTAI is not legally binding, it offers a valuable framework for operationalising ethical reflection in practice. ACHILLES will consider using ALTAI as a reference point to support the ethical dimensions of system development, validation, and pilot deployment. In this way, the Project contributes not only to technical innovation but also to the broader effort of building AI that is safe, lawful, and aligned with European values.

6.1 Relevance of the AI Act for ACHILLES

The ACHILLES project falls within the scope of activities covered by the AI Act, particularly in the development and deployment of systems that could be classified as high-risk. Several use cases under ACHILLES, including healthcare applications, identity verification systems, and automated content generation tools, interact directly with domains identified as high risk under the AI Act. In addition, some components developed within ACHILLES may also fall under the limited-risk category, especially those involving conversational AI systems such as chatbots or copilots. These systems are subject to specific transparency obligations under the AI Act, requiring users to be clearly informed when they are interacting with an AI system. While transparency-related risks and safeguards for these systems are addressed in greater detail in Deliverable D4.1, their regulatory implications remain a relevant consideration throughout the project lifecycle.

Specifically, the following obligations under the AI Act are particularly relevant for ACHILLES:

- Article 9: Risk Management System. ACHILLES must implement continuous and proactive risk management procedures to identify, evaluate, and mitigate risks associated with the AI systems developed, particularly in the healthcare and ID verification use cases. An initial identification

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of risks associated with the Project has been conducted by ETICAS and will be continuously monitored throughout the Project.

- Article 10: Data and Data Governance. Data used to train, validate, and test AI systems must be relevant, representative, free of errors as far as possible, and must respect the rights of individuals. This is crucial for pilots relying on health datasets and biometric data, where bias, underrepresentation, or inaccuracy could lead to discriminatory outcomes.
- Article 11: Technical Documentation. ACHILLES must ensure that each AI system is accompanied by detailed technical documentation, describing the design, development process, intended use, performance limitations, and risk mitigation measures. This requirement will directly impact deliverables related to system integration and validation.
- Article 12: Record-Keeping. Appropriate logging of system behaviour and decision-making processes must be embedded to allow traceability of system outcomes and facilitate accountability.
- Article 13: Transparency and Provision of Information to Deployers. ACHILLES must guarantee that the AI's output is sufficiently transparent for deployers to interpret a system's output and for its subsequent appropriate use. This is particularly important for high-risk AI systems.
- Article 14: Human Oversight. AI systems developed must include measures that ensure meaningful human oversight to prevent or minimise risks to health, safety, and fundamental rights. This is especially critical in the healthcare pilots and identity verification systems.
- Article 15: Accuracy, Robustness, and Cybersecurity. Systems must achieve a high level of accuracy and resilience against attacks or manipulation. In use cases like healthcare diagnostics or biometric ID, this requirement is essential to maintain trustworthiness and avoid harm.

The AI Act is highly relevant for ACHILLES because many of the project tasks address aspects that the regulation considers essential for high-risk AI systems. In WP1, tasks that focus on bias detection and data auditing ensure that the datasets used are accurate, representative, and thoroughly documented, thereby supporting robust data governance and transparency in line with the Act's expectations. WP2 reinforces this foundation by embedding advanced data protection strategies such as automated detection of personal data, effective pseudonymisation methods, and federated learning approaches. These methods enhance data security and privacy while also contributing to the traceability and accountability requirements of the regulation. In WP3, efforts to improve system efficiency through strategies like model recycling, finetuning, and the integration of multi-agent systems contribute to overall system robustness and clear documentation of decision processes.

WP4 further strengthens ethical and regulatory compliance through the mapping and integration of international and EU legal frameworks, value-sensitive design research, and comprehensive ethics management protocols, all of which uphold the principles of transparency, human oversight, fairness, and accountability. WP5 establishes a technical infrastructure for providing clear explanations of AI decisions, managing uncertainty, continuously monitoring system performance, and automating reporting processes so that system integrity and user trust are maintained. WP6 then integrates these

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components into the ACHILLES Integrated Development Environment, ensuring effective communication between system elements and facilitating clear user interactions through well-designed interfaces and a virtual assistant. Finally, WP7 validates the practical deployment of AI systems in use cases that span healthcare, pharmaceuticals, identity verification, and content creation, employing a structured validation protocol and the inspection process to verify that all ethical and regulatory safeguards function effectively in real-world settings. In this way, ACHILLES is committed to embedding the AI Act's requirements throughout the project lifecycle to ensure that its AI systems are developed in a safe, transparent, and human-centric manner.

6.2 Application of AI Act in ACHILLES

The classification of risks under the AI Act shapes how technical partners approach modular system design, particularly in relation to transparency, documentation, and human oversight. Task 5.1 already incorporates these elements into the integration roadmap, paying attention to how each module supports traceability, explainability, and responsiveness to user input. Rather than treating these as final product features, the Project is embedding them within the architecture itself.

The AI Act also serves as a reference point for internal dialogue around accountability and fairness. Partners are encouraged to assess whether their systems introduce risks of exclusion, opacity, or performance disparities across different groups. These considerations are being addressed collaboratively with support from WP1 and legal partners, especially in tasks where automated decisions could affect access to services or shape user interaction.

To support this alignment, ACHILLES can use the ALTAI principles as an internal ethical guide. While not formally required, this framework offers a structured way to reflect on the societal impact of the system, and to identify where additional safeguards or clarification might be necessary, whether in documentation, user-facing design, or evaluation criteria.

Where legal assessments such as Data Protection Impact Assessments (DPIAs) or fundamental rights reviews become relevant, they will be scoped and implemented based on the actual risks identified during development and pilot preparation. These steps are being considered, but not assumed, as the regulatory and technical requirements continue to evolve in parallel.

7 OTHER ETHICAL REQUIREMENTS IN AI RESEARCH

7.1 Requirements for Research Conducted in Third Countries

While all of the ACHILLES research will take place within the EU, partners must remain attentive to the ethical and legal implications of any activities, whether technical development, data collection, or dissemination, that involve third countries. Research conducted outside the EU must respect the same ethical principles that apply within it. This includes ensuring that participants are informed of their rights, that data protection standards are upheld, and that local vulnerabilities are not exploited in

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pursuit of research objectives. In particular, partners must consider whether data subjects in third countries are granted equivalent protections under local law, and if not, whether additional safeguards are required to ensure fairness and respect for rights.

The transfer of data to or from third countries must be treated with caution. In accordance with GDPR provisions and ethical best practice, transfers should only occur if the destination offers adequate data protection or if specific safeguards (such as standard contractual clauses or explicit consent) are in place (Art.44 GDPR)[12]. Even where legal mechanisms are satisfied, partners must reflect on the ethical risks of outsourcing data processing or engaging with populations outside the European regulatory space, especially where power imbalances or limited recourse mechanisms may exist. In all cases, ACHILLES partners should be guided by the principles of proportionality, necessity, and fairness (Art.5 GDPR). Research conducted in third countries should demonstrate a clear benefit to those involved, minimise the risk of harm, and avoid creating ethical double standards between jurisdictions.

8 ETHICAL CONSIDERATION IN PILOT IMPLEMENTATION AND PROJECT LIFECYCLE

The ACHILLES pilot activities represent a critical phase in which research outputs are tested in real-world conditions (WP7). This phase brings specific ethical responsibilities, as it involves direct engagement with individuals, context-specific data collection, and the deployment of AI systems that can affect perceptions, behaviours, or outcomes. The four pilot domains (healthcare, pharmaceuticals, ID verification, and content creation) each pose distinct ethical challenges that require attention to context, sensitivity to risk, and readiness to adapt.

Ethical oversight during the pilot phase begins with proper planning. Each pilot must ensure that consent procedures are adapted to the environment in which participants will interact with the AI systems. Consent forms and information sheets should describe not only the nature of the research but also how the system operates, what data it will collect, and whether the system's outputs may impact users directly or indirectly[13]. In cases where the interaction is passive, such as observational data, or where participants may not fully understand the scope of AI inference, researchers have an ethical obligation to ensure that understanding is supported with accessible language and real-time clarification when needed.

In the **healthcare** and **pharmaceuticals** pilots, particular care must be taken with regard to sensitive health data. According to the GDPR, health data is classified under Article 9 as special category data, which requires explicit consent and strengthened safeguards for processing. Data minimisation and

12 In accordance to recital 101 (GDPR) which reinforces the ethical need to consider differences in legal systems.
13 See Recital 32 GDPR, which stipulates the right to withdraw consent, the requirement for affirmative consent, and that the data subject must understand what they are consenting to

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purpose limitation are essential, and any clinical inference made by AI systems must be accompanied by clear documentation and justified use.

From an ethical standpoint, the pilot must also take into account the Horizon Europe emphasis on non-discrimination and the right to physical and mental integrity. The AI Act reinforces this by requiring transparency and human oversight in systems that support or simulate medical decision-making. Even if the system does not replace a clinical actor, it should not create over-reliance, opaque risk scoring, or confusion for users. Patients and professionals must be able to understand the system's function, challenge its output, and access alternatives where appropriate.

In the **ID verification** pilot, ethical concerns centre on data security, biometric information, and the risk of exclusion. Under both the GDPR and the AI Act, this is considered a high-risk domain. Article 9 of the GDPR explicitly classifies biometric data used for identification purposes as sensitive data, requiring a lawful basis for processing, as well as heightened safeguards. These may include explicit and informed consent, clear documentation of data flows, and rigorous protection against unauthorised access.

From an ethical perspective, identity systems raise risks that go beyond privacy. As highlighted by Horizon Europe's ethics framework, the pilot must ensure that the design and deployment of the system respects the principles of dignity, fairness, and non-discrimination (Art. 19 GDPR). These concerns are especially relevant in biometric systems, which may underperform across different demographic groups or exclude individuals whose biometric features are difficult to capture reliably. The AI Act reinforces this by requiring bias mitigation strategies, continuous performance monitoring, and mechanisms for human oversight[14].

The **content creation** pilot introduces its own ethical landscape, especially around authorship, representation, and the use of personal or semi-structured input data to train generative models. The GDPR applies if personal data is used to train or guide content generation, even if indirectly. Partners must assess whether training datasets include identifiable information, and whether individuals could be re-identified through style, context, or metadata. If so, informed consent and data minimisation measures must be in place. Reuse of personal or publicly available data must also be evaluated under Article 6 and Article 14 of the GDPR, particularly if data subjects were unaware their content could be used in this way.

From an AI Act perspective, this pilot may not qualify as high risk by default, but it still requires ethical alignment and transparency obligations. Generative systems must avoid creating outputs that reinforce stereotypes, misrepresent individuals, or circulate harmful content. Horizon Europe's ethical

14 See Art,9, Art, 14 and Art,17 of the AI Act, which set requirements of bias mitigation, human oversight, and continuous monitoring for systems categorized as high- risk.

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framework requires that projects reflect on the potential societal consequences of their tools, including issues of representation, authorship, and misuse.

All pilots must build in mechanisms for ethical monitoring throughout the deployment phase. This includes tracking how participants engage with the system, whether their expectations are being met, and whether any discomfort, confusion, or concerns emerge during use. Similarly, it also requires a willingness to revise activities and seek guidance from the ethical and legal partners, if any questions arise. Each pilot team should maintain open channels for feedback and document how ethical issues are raised and resolved.

The ACHILLES pilots will also play a key role in refining the Project's understanding of ALTAI principles, particularly human agency, fairness, transparency, and accountability. These principles must be translated from abstract guidelines into actual safeguards during pilot deployment. For example, users should be able to understand the logic behind system outputs, correct errors where possible, and know where to turn if they feel harmed or misrepresented by the technology.

In line with these ethical expectations, the Project also acknowledges that fairness, transparency, explainability, accountability, and trustworthiness must be reflected not only in pilot protocols but also in the system's architectural backbone. These core AI principles, as referenced explicitly in Task 5.1, are vital to the legitimacy and societal acceptance of ACHILLES technologies. Their interpretation, however, cannot be left to technical metrics alone.

Therefore, D4.4 anticipates the development of joint ethical-legal framing documents, with the participation of partners such as ETICAS, AXIOLOGIC, FhAICOS, CUOMOIT and ARCADA, and drawing insights from D4.1 led by KUL, to ensure that these principles guide both the technical implementation and the decisions taken at each stage of the system lifecycle. While engineers will define operational indicators and mechanisms, the ethical assumptions that give a basis for those definitions must remain visible and explainable throughout. Further elaboration will follow in coordination with WP5, WP6, and WP7, supported by the ethical contributions of WP1.

Bias detection and mitigation will be another cornerstone of ethical system design. As laid out in T1.2, technical partners are developing approaches to identify statistical patterns of bias across datasets and model outputs. Yet bias it raises deeper questions about representation, historical inequalities, and the implications of classification. D4.4 recognises that ethical criteria must inform how detection thresholds are set, how mitigation is prioritised, and how performance trade-offs are evaluated. These reflections will be developed further through collaboration with WP1, ethical input and legal analysis throughout the Project's lifecycle.

To support this interdisciplinary process, the system architecture includes dedicated interfaces and feedback loops that allow non-technical assessments of fairness and bias to shape decision-making. This will be particularly relevant during validation phases and user testing, where systems must perform reliably and equitably across diverse conditions.

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Finally, in preparation for deployment, ACHILLES anticipates the possible need to conduct a Data Protection Impact Assessment (DPIA) under the GPDR and a Fundamental Rights Impact Assessment (FRIA) under the AI Act. While legal frameworks will be detailed in D4.1, D4.4 acknowledges that ethical risk assessments must begin early. These tools are vital for identifying and addressing risks related to privacy, discrimination, and fundamental rights. This is particularly relevant, especially within pilot execution that involves personal data and sensitive populations.

9 ETHICS ISSUES IN DISSEMINATION ACTIVITIES

Dissemination is a core component of ACHILLES. It ensures that research results, tools, and lessons learned reach the broader community, including researchers, developers, policymakers, and the public. However, dissemination also carries ethical responsibilities, especially when it involves sharing information derived from human participants, AI systems trained on sensitive data, or materials produced through real-world testing.

When using images, audio, or video recordings of individuals, explicit and informed consent must be obtained in advance. This includes presentations at conferences, publication on websites, and social media posts. Even when individuals appear in group settings or are not named, ethical use still requires considering whether they could be recognised or affected by the context in which the material is shared.

When organising events, partners are encouraged to design spaces and documentation practices with ethics in mind. This may include using signage to indicate where photography or filming will take place, offering badges or stickers to identify individuals who do not wish to be recorded, and reminding staff and external service providers of these rules. Images should focus on activities, environments, or materials, rather than faces, unless individuals have clearly agreed to appear and have understood how their image will be used.

ACHILLES partners must also avoid disseminating content that could misrepresent findings, overstate results, or obscure risks. Ethical communication means being transparent not only about successes but also about limitations and uncertainties. This is especially important when describing AI functionalities or system capabilities. Where prototypes are still under development, or pilot results are preliminary, this should be clearly stated to avoid creating unrealistic expectations. Finally, before publishing or publicly sharing project outputs, partners must follow internal procedures for approval and ensure that no sensitive deliverables are disclosed in violation of the classification outlined in the Grant Agreement.

10 FUTURE ACTIONS

This first version of the Ethics Guidelines has outlined the ethical foundations and practical expectations for responsible research and innovation across the ACHILLES project. From data protection and informed consent to ethical AI deployment and public communication, the guidelines

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are intended to support partners in making decisions that are not only compliant with formal requirements, but aligned with the broader values of dignity, fairness, and accountability.

Partners are encouraged to return to these guidelines regularly, and to treat ethics as a continuous process. Questions about risk, fairness, representation, or unintended consequences should be raised early, and addressed through open dialogue and shared reflection. The ACHILLES consortium includes legal, technical, and ethical expertise, and all partners are expected to contribute to and benefit from that exchange.

A revised version of these guidelines will be issued in Month 28 (M28). That version will build on the lessons learned during the first half of the Project, including insights gathered from pilot implementation, participant engagement, and any emerging regulatory or societal developments. It will also incorporate feedback from partners and reflect any changes in ethical expectations or standards affecting AI research in the EU context.

Ultimately, the strength of ACHILLES lies not only in its technical innovation but in its capacity to build trust through responsible design, transparent communication, and ongoing ethical vigilance. These guidelines mark the starting point of that commitment.

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