equicares

COMMUNITY-DRIVEN INCLUSIVE, EQUITABLE, MENTAL HEALTHCARE ACCESS

D9.3 Regulatory, societal, ethical and gender issues plan - v1

White Research (WR)

30/04/2025

Funded by the European Union

Document Information

Issued by:	WR
Issue date:	30 April 2025
Due date:	30 April 2025
Work package leader:	White Research (WP9)
Dissemination level:	PU - Public

Document History

Version	Date	Modifications made by
ToC	17/03/2025	Table of Contents shared with the Ethics Advisory Board (EAB)
0.1	15/04/2025	1st draft shared with consortium partners, the Ethics Advisory Board (EAB) and the External Ethics Advisor (EA)
0.2	25/04/2025	2nd draft integrating feedback from consortium partners, Ethics Advisory Board (EAB) and External Ethics Advisor's (EA)
1.0	30/04/2025	Final version submitted to the EC Portal

Authors

Name(s)	Beneficiary
Artemis Psaltoglou	WR
Konstantina Mataftsi	WR
Pinelopi Kaslama	WR
Christian Hauschildt	WR

In case you want any additional information, or you want to consult with the authors of this document, please send your inquiries to: apsaltoglou@white-research.eu, kmataftsi@white-research.eu

Quality Reviewers

Name(s)	Beneficiary
Ioannis Kiriakidis	External Ethics Advisor (EA)
Ana Vivas (EAB member & Pilot partner)	SEERC
Jeff Moore (EAB member)	JIGSAW
Laure-Anne Denouel (Pilot partner)	LADAPT
Giorgos Charitakis (Pilot partner)	GIVMED
Marta Lima Serrano (Pilot partner)	FISEVI
Stavros Theocharis	SQUAREDEV
Kathrin Exner (Pilot partner)	ZI
Sara Canella	EHTEL
Mira Fey (Pilot partner)	LGBTI

Executive Summary

The present deliverable (D9.3 Regulatory, societal, ethical, and gender issues plan – v1) constitutes the initial version of the **Ethics Handbook of the EQUICARES** project, funded by the European Union's Horizon Europe Research and Innovation programme. EQUICARES aims to enhance access to innovative and sustainable mental health services for people in vulnerable situations by integrating research, co-creation, and policy solutions. The project employs advanced methodologies to evaluate and improve mental healthcare accessibility, offering data-driven insights and tools for policymakers.

The Regulatory, societal, ethical, and gender issues plan - referred to henceforth as Ethics Handbook - falls under Work Package 9 (WP9) – Task 9.3 and is scheduled for submission by Month 4 (M4) of the project timeline.

In this context, the first version of the Ethics Handbook has been developed to guide the ethical conduct of research and participatory activities involving people in vulnerable situations (PVS) as well as the ethical design and deployment of the AI-based Assistant within the EQUICARES project. It outlines critical ethical, regulatory, societal, and gender-related principles relevant to project activities, emphasizing adherence to relevant EU, international, and national regulatory frameworks and policies.

The handbook provides detailed context-sensitive guidelines for engaging diverse populations in vulnerable situations, including LGBTQIA+ people, individuals with physical and intellectual disabilities, migrants, refugees, Roma, older persons, and youth, as participants as co-creators. It prioritises their protection, dignity, and empowerment and promotes inclusive and respectful engagement strategies.

Ethical challenges specific to AI are also addressed, with a focus on identifying and mitigating risks such as algorithmic bias, transparency, data protection and accountability. The handbook highlights governance mechanisms for ethical oversight, establishing clear roles and responsibilities through structures such as the Ethics Advisory Board, the Ethics Advisor, and periodic ethical audits. These measures aim to ensure continuous ethical compliance, reflexivity, and integrity across all stages of the EQUICARES project.

Table of Contents

1. INTRODUCTION 4

1.1 PROJECT CONTEXT 4
1.2 PURPOSE AND SCOPE 5
1.3 INTERRELATIONS WITH OTHER DELIVERABLES 5
1.4 STRUCTURE OF THE HANDBOOK 6

2. ETHICAL PRINCIPLES FOR RESEARCH AND INTERVENTION ACTIVITIES INVOLVING PVS 7

2.1 RESEARCH INTEGRITY, TRANSPARENCY, AND HONESTY 7
2.2 DEFINITION OF PVS IN EQUICARES 8
2.3 RESEARCH AND PILOT DESIGN AND IMPLEMENTATION 11
2.3.1 Research and intervention activities involving PVS 11
2.3.2 Ethical considerations of research and intervention activities involving PVS 12
2.3.3 Ethical guidelines for engaging with PVS 13
2.3.4 Protocol for incidental findings and referrals 18

3. ETHICAL AND REGULATORY FRAMEWORK 20

3.1 INTERNATIONAL AND EU POLICIES 20
3.1.1 Mental health and clinical practice 20
3.1.2 Inclusion and protection of People in Vulnerable Situations (PVS) 22
3.1.3 Data, Artificial Intelligence and Cybersecurity 25
3.1.4 National policies 27

4. ETHICS AND GENDER ASPECTS OF THE AI-BASED ASSISTANT 51

4.1 PURPOSE AND FUNCTION 51
4.2 THE EUROPEAN APPROACH: ETHICS GUIDELINES FOR TRUSTWORTHY AI 51
4.3 ETHICAL ISSUES IN DEVELOPMENT AND DEPLOYMENT 53
4.3.1 AI-specific risks and mitigation measures 53
4.3.2 Handling of user-generated content and potential misuse 57
4.4 GENDER DIMENSION IN AI APPLICATION 58
4.4.1 Gender analysis framework 58
4.5 AI IMPACT ASSESSMENT 60
5.1 ETHICS ADVISORY BOARD 63
5.2 EXTERNAL ETHICS ADVISOR 63
5.3 ROLES AND RESPONSIBILITIES 64
5.4 ETHICS REVIEW & APPROVAL PROCEDURES AT THE PILOT SITES 65
5.5 ETHICAL OVERSIGHT AND COMPLIANCE 66

6. CONCLUSIONS 67

7. REFERENCES 68

8. ANNEXES 70

8.1 ETHICS ISSUE LOG TEMPLATE 70
8.2 ETHICAL AUDIT TEMPLATE 71
8.3 INCIDENTAL FINDINGS LOG TEMPLATE 73

List of Tables

Table 1. Terms and Definitions 2
Table 2. Comparison of legal, regulatory, policy, and ethical frameworks 4
Table 3.International and EU policies on mental health and clinical practice 18
Table 4.International and EU policies on inclusion and protection of PVS 20
Table 5.International and EU policies on data, AI and Cybersecurity 23
Table 6.Relevant national policies in Ireland 25
Table 7.Relevant national policies in Spain 30
Table 8.Relevant national policies in France 36
Table 9.Relevant national policies in Germany 41
Table 10.Relevant national policies in Türkiye 42
Table 11.Relevant national policies in Greece 43
Table 12.Relevant national policies in Bulgaria 48
Table 13.Ethical impact assessment of the AI-based Assistant 58
Table 14 Ethical approval processes for pilot partners 61

List of Terms and Definitions

Table 1. Terms and Definitions

Abbreviation	Definition
AI	Artificial Intelligence
APA	American Psychological Association
EA	External Ethics Advisor
EAB	Ethics Advisory Board
EIGE	European Institute for Gender Equality
ENISA	European Union Agency for Cybersecurity
LGBTQIA+	Lesbian, Gay, Bisexual, Transgender, Queer or questioning, Intersex, Agender and additional identities
LLM	Large Language Model
PVS	Persons in Vulnerable Situations
T	Task
UN	United Nations
UNICEF	United Nations International Children's Emergency Fund
WHO	World Health Organization
WP	Work Package
WPATH	World Professional Association for Transgender Health

1. Introduction

1.1 Project context

EQUICARES supports access to innovative and sustainable mental health and care services by people in vulnerable situations through a blend of research, co-creation and policy solutions. The project uses innovative methodologies, such as an advanced application of Levesque framework for evaluation of mental health services; the deployment of Computational Social Sciences to increase access for hard-to-reach populations in vulnerable situations and collect accurate quantitative and qualitative data on inequalities and opportunities in mental healthcare services; and the combination of complementary cost-analysis techniques. To unlock the design of innovative solutions, the project maps, through digital ethnography, existing innovative solutions, analyses for accessible mental health services and links them with different parts of the mental health system. Such informative insights are visualised and offered to policymakers through a dedicated Atlas and a policy Dashboard.

EQUICARES pilots innovative solutions in 8 areas from 7 countries, which represent diverse socioeconomic and healthcare settings and cover a wide range of vulnerability factors, while informing various strategic frameworks of the EU. Through “Smart Health Labs”, the project engages people in vulnerable situations at the community level to codesign, implement and assess innovative solutions based on the principles of social economy and user innovation. At the individual level, the project provides awareness-raising and capacity-building and pilots a novel AI-based Assistant, making advancements in the landscape of AI-generated mental health ecosystem, and fostering mental health and digital literacy of users. EQUICARES tests the value of its innovative solutions and applies novel cost analysis techniques to provide solid evidence of the negative impact of *no action*. Finally, the project aims to replicate its outcomes in 4 additional cases and to develop the Inclusive Mental Health and Care Policy Dashboard towards the sustainability and policy uptake of its results.

The project’s mission is to address systemic inequalities through interdisciplinary research, participatory innovation, and policy engagement across the selected pilot sites. The main objectives of the EQUICARES project are to:

- O1: Identify and analyse health inequalities and access barriers to mental health services of people in vulnerable situations across the healthcare system (prevention, primary, secondary, tertiary, integrated, long-term) by collecting reliable and granular data at macro-, meso-, and micro-level.
- O2: Identify innovative solutions that promote access to mental health services, evaluate their outcomes, effectiveness, costs, ability to address factors of inequality, and limitations in enhancing service access, and make them available to policymakers and care workers through the Atlas.
- O3: Put the people in vulnerable situations at the centre of innovation activities by engaging them in local “Smart Health Labs” and empowering them through a health promotion programme and an AI-based Assistant that aims at enhancing their mental health and digital literacy, while also supporting and engaging the supply side actors.
- O4: Co-design and pilot innovative solutions in the 8 pilot sites to improve accessibility to mental health services by boosting the abilities of people in vulnerable situations to access care services and the capacity of healthcare systems to provide accessible, cost efficient and quality services.

- O5: Monitor and evaluate the multi-level impact of pilot interventions (e.g., higher equity, monetary savings, social cohesion) as well as the costs of not taking measures through complementary cost analysis techniques.
- O6: Ensure that policy and decision makers have enhanced access to quality data, helping them to identify barriers to service access, the unmet needs of people in vulnerable situations, as well as relevant innovations, and produce evidence-based recommendations towards the scale-up and replication of our results.
- O7: Ensure that the project's results are properly disseminated to and exploited by core stakeholder groups (e.g., policy makers, mental health care workers, service providers, representatives of disadvantaged groups), with a view to ensuring the sustainability of the EQUICARES portfolio of innovative solutions.

To achieve these objectives, a comprehensive set of research and participatory activities has been designed. Several of these involve direct interaction with human participants or the collection and processing of personal and sensitive data, especially of people in vulnerable situations (PVS). The activities involving PVS require careful ethical consideration, and as such, they constitute the primary focus of this Ethics Handbook, together with the AI-based Assistant and pilot clinical study.

1.2 Purpose and scope

This report '*D9.3 Regulatory, societal, ethical and gender issues plan - v1'* constitutes the first version of the EQUICARES Ethics Handbook, which serves as a guiding document for the research and participatory project activities, with emphasis on the pilot interventions and on the pilot clinical study with the AI-based Assistant. It outlines the ethics-related and safety-related issues, and it provides a comprehensive overview of the relevant policy framework at the international, EU and national level (countries where pilot interventions will take place). This overview of the policy framework incorporates all applicable conventions at these levels, including legal, regulatory and ethical dimensions. Table 2 outlines the key differences between legal, regulatory, policy, and ethical approaches, highlighting their definitions, binding nature, focus areas, and practical examples. It helps clarify how these frameworks interact and complement each other in shaping responsible research and innovation, particularly in contexts involving AI, health, and human rights.

Table 2. Comparison of legal, regulatory, policy, and ethical frameworks

Dimension	Definition	Binding	Focus	Example
Legal	Codified laws and rights	✓ Legally binding	What is lawful	GDPR, Disability Acts
Regulatory	Operational rules to enforce laws	✓ Legally binding	How laws are applied and monitored	GDPR guidelines from data authorities
Policy	Strategic priorities and non-binding goals	✕ Usually not	What an institution wants to achieve	National AI, health or inclusion strategies
Ethical	Moral standards and values	✕ Not binding	What is right or responsible	Helsinki Declaration

1.3 Interrelations with other deliverables

This report is the deliverable of the Task 9.3: Regulatory, societal, and ethical issues – 1st period (M1-M18), which is then continued as Task 10.3: Regulatory, societal, and ethical issues – 2nd period

(M19-M36) and then as Task 11.3: Regulatory, societal, and ethical issues – 3rd period (M37-M48). All these tasks are dedicated to ethical compliance of EQUICARES activities.

An updated version of this report will be developed in the middle of the project, D10.3 (due at M24). The second version will integrate lessons learned during the first implementation phase, especially from the annual ethical audits and the ethical issues encountered as well as the actions taken during the first two years of the project. At the same time, it will provide updated guidelines informed by the preliminary results of WP1, 2, 3 and 4, which are expected to provide a better overview of the pilot interventions.

Deliverable D9.3 is also closely linked to other key deliverables and tasks focused on ethical and regulatory compliance, data management, and informed consent procedures. Specifically, it aligns with:

- **Data Management Plan (DMP)**: encompasses detailed guidelines on handling personal data, informed consent forms, and privacy safeguards, complementing the ethical considerations described in this handbook. Three versions of the DMP are D9.2 due in M3, D10.2 due in M24, and D11.2 due in M48, as the results of T9.2, T10.2 and T11.2 respectively.
- **WP12 – Ethics Deliverables**: focus on specific ethical, data protection, and AI-related requirements, ensuring alignment and consistency across all project activities involving the establishment of the EAB, the appointment of the EA, and EA's reports on ethical compliance.

These tasks work in a complementary way, and together they establish a comprehensive framework to ensure consistent ethical compliance throughout the EQUICARES project.

1.4 Structure of the handbook

The Ethics Handbook is structured into the following main sections:

- Section 1 introduces the reader to the handbook, by defining the project context, objectives, and scope, as well as outlining interrelations with other deliverables.
- Section 2 presents the ethical principles for research and intervention, describing ethical considerations, guidelines, and procedures for engaging with diverse PVS.
- Section 3 outlines the ethical and regulatory framework, through a comprehensive overview of applicable international, EU, and national regulatory frameworks governing mental health, vulnerable populations, data protection, and AI use.
- Section 4 discusses the ethics and gender aspects of the AI-based Assistant, providing ethical guidelines for the design, development and testing, as well as an impact assessment, with the relevant risks and mitigation measures of the AI Assistant.
- Section 5 presents the ethics governance and oversight of EQUICARES, describing the established governance structures, including the Ethics Advisory Board, and the internal mechanisms for ethical monitoring and compliance.
- Section 6 outlines key considerations.
- Section 7 lists the references used for the present deliverable.
- Section 8 includes the Annexes, with templates for the Ethical Issue Log and Incidental Findings Log appended.

2. Ethical principles for research and intervention activities involving PVS

This section outlines the main ethical principles and frameworks that guide and ensure the EQUICARES research and pilot activities. In particular, the EQUICARES definition of PVS targeted at the pilot interventions and population-specific ethical considerations, as well as the main activities that involve data collection with human participants and/or personal data for PVS, and the corresponding ethical guidelines and procedures that will be followed.

2.1 Research integrity, transparency, and honesty

EQUICARES is committed to the highest standards of **research integrity** and upholds the principles of **transparency, accountability, and honesty** across all its research and innovation activities. These principles apply to all individuals involved in the project, including students, researchers, developers, pilot partners, technical staff, and communication teams.

The project embraces the **European Code of Conduct for Research Integrity** (ALLEA, 2017/2023) and the **European Charter for Researchers and The Code of Conduct for the Recruitment of Researchers** (European Commission, 2005), and aligns with internationally recognised human rights frameworks, including:

- The **EU Charter of Fundamental Rights**, which guarantees freedoms such as dignity, equality, and the right to privacy and personal data protection.
- The **European Convention on Human Rights**, particularly Article 8 (right to respect for private and family life) and Article 10 (freedom of expression, including scientific freedom).
- The **UN Universal Declaration of Human Rights**, especially Articles 19 (freedom of opinion) and 27 (right to participate in scientific advancement).
- The **UN Convention on the Rights of Persons with Disabilities (UN CRPD)**, which promotes accessible and inclusive research participation for all individuals, especially those in vulnerable situations.

These frameworks are presented in detail in the following section. Altogether, they guide how EQUICARES designs, conducts, and communicates research in ways that uphold human dignity, non-discrimination, and the right to participate equally in science and innovation.

As part of its commitment to research integrity and responsible conduct, EQUICARES promotes inclusive recruitment practices for all researchers and staff engaged in the project. This includes transparent, equitable selection processes that foster diversity across gender, ethnicity, age, ability, and other dimensions of identity. Particular attention is given to encouraging the participation of individuals from underrepresented groups, in line with the project's broader objectives of inclusion and equity. Inclusive recruitment strengthens the ethical foundation of the project by enriching perspectives, enhancing cultural competence, and reinforcing the social value of research (European Commission, 2005).

This internal commitment is further reflected in the strong gender balance across the consortium, with women actively involved in coordination, technical development, and leadership roles. Their engagement since the early conceptualisation stages of EQUICARES highlights the project's

alignment with the European Commission's priorities on gender equality in research and innovation (European Commission, 2020), as well as broader principles of fairness and accountability in research environments (European Commission, 2005; ALLEA, 2017/2023).

Moreover, the consortium partners are committed to ensure research transparency and honesty. To maintain **transparency**:

- All research methodologies, data collection processes, and limitations are documented and made available to relevant stakeholders.
- Participants are fully informed about the purpose, scope, and implications of their involvement, with informed consent obtained and documented.
- Research findings are reported accurately, avoiding fabrication, falsification, or misrepresentation of data or results.

To ensure **honesty**:

- All contributors are appropriately acknowledged in project outputs and publications.
- Authorship is assigned based on substantial contributions, in accordance with international academic standards[1]. Gift authorship (adding individuals who did not make a substantial contribution) or ghost authorship (omitting someone who made a significant contribution (often in cases of professional writing or research assistance) is strictly prohibited.
- Conflicts of interest will be disclosed and managed to prevent bias.

All EQUICARES partners are expected to actively uphold the project's shared ethical values and contribute to a responsible research culture. The following core principles must guide each team's work throughout the project:

- ❖ Uphold research ethics and integrity policies internally by ensuring all activities are conducted with transparency, honesty, and accountability.
- ❖ Ensure inclusive recruitment by adopting fair and transparent hiring practices that support gender balance and the inclusion of people from under-represented social groups.
- ❖ Promote gender equity in project implementation, recognising and supporting the active role of women in leadership, technical, and research activities.
- ❖ Guarantee transparency in research processes, including clear documentation of methodologies, data handling, and informed consent procedures.
- ❖ Ensure honesty in authorship and reporting, by crediting all substantial contributions, avoiding misrepresentation, and explicitly prohibiting gift or ghost authorship.

These principles are not only ethical obligations but essential to the credibility, inclusivity, and impact of EQUICARES.

2.2 Definition of PVS in EQUICARES

Based on the definition provided by the United Nations office for Disaster Risk Reduction (UNDRR)[2], vulnerability refers to the conditions determined by physical, social, economic, and environmental factors or processes which increase the susceptibility of an individual, a community, assets or systems to the impacts of hazards. As far as individuals and communities are concerned, it is clear that some

[1] International Committee of Medical Journal Editors (ICMJE). *Recommendations for the Conduct, Reporting, Editing, and Publication of Scholarly Work in Medical Journals*. Updated 2023. Available here.

[2] UNDRR (2025). Sendai Framework Terminology on Disaster Risk Reduction, Available here.

population groups are more vulnerable due to characteristics such as age, gender and sexual identities, ethnicity, culture, religion, intellectual and physical disability, socio-economic status, geographical location, or migration status (WHO, 2025).

In EQUICARES, the **specific characteristics of research participants will be finalised by research partners at the beginning of each qualitative and quantitative study in line with the objectives and research design.**

Overall, the populations that are going to be involved in the research and intervention activities are presented below, together with specific ethical considerations that must be acknowledged and addressed:

1. **LGBTQIA+ people:**
    - Mistrust of institutions and risk of stigma or discrimination in healthcare and research settings.
    - Concerns over confidentiality, particularly regarding sexual orientation or gender identity in environments where these may be socially or legally sensitive.
    - Need for inclusive language and gender-affirming practices in data collection and AI interactions (see below section on gender-affirming practices).
2. **Individuals with physical and intellectual disabilities:**
    - Accessibility barriers (physical, cognitive, sensory) require adapted tools, materials, and formats.
    - Capacity to consent must be assessed carefully, with clear communication aids and, where appropriate, supported decision-making.
    - Risk of stigma or discrimination in healthcare and research settings; people with physical and intellectual disabilities may not be listened to and may be hidden under their disability.
3. **Refugees and asylum seekers[3]:**
    - Legal and psychosocial vulnerability, including fear of authorities, trauma or ongoing legal proceedings.
    - Language barriers and the need for cultural mediation.
    - Risk of retraumatisation, especially during discussions of past events or mental health experiences.
    - Consideration of cultural norms and beliefs, in particular regarding mental health.
    - Risk of misdiagnosis and medical discrimination ("Mediterranean Syndrome"), a form of institutional racism, where symptoms of migrants, especially from North Africa, are sometimes dismissed as exaggerated or non-organic, leading to inadequate care or neglect (Fassin, 2001).
4. **Migrants and individuals with a migrant-background:**
    - Mistrust of institutions and fear of discrimination or surveillance.
    - Cultural differences in mental health expression and help-seeking behaviours.
    - Need to adapt digital and intervention tools to culturally diverse health literacies.
    - Risk of biased treatment or underdiagnosis related to racialized stereotypes, including phenomena such as the "Mediterranean Syndrome," where the mental health

[3] In the context of EQUICARES, references to refugees and asylum seekers are understood broadly, including not only individuals officially recognized under the 1951 Geneva Convention but also beneficiaries of subsidiary protection and others in vulnerable migratory situations. This inclusive approach ensures that support is offered based on actual vulnerability and need, regardless of formal legal status.

concerns of migrant-origin populations may be underestimated or misinterpreted by healthcare providers (Fassin, 2001).

5. **Ethnoreligious minorities:**
   - Risk of exclusion or stereotyping, particularly if past policies have been discriminatory.
   - Importance of respecting religious and cultural norms, including in how care or mental health is framed.
6. **Roma community:**
   - Historical and systemic marginalization and discrimination, leading to deep mistrust in healthcare systems, research and authorities.
   - Low access to digital tools, health services, and safe environments.
7. **Older people:**
   - Risk of ageism, especially in digital literacy.
   - Digital divide, AI-based assistant must be accessible and user-friendly for older users.
   - Possible cognitive decline affecting consent; isolation may impact willingness or ability to participate.
   - Consider accessibility issues related to mobility issues and other age-related physical changes (e.g., vision, audition).
8. **Youth populations[4], unaccompanied minors:**
   - Power imbalances and heightened duty of care.
   - Use youth-friendly approaches to increase understanding and engagement.
   - Cultural awareness in group interventions of unaccompanied minors.
   - Legal restrictions on consent, as parental or guardian consent is often required.
   - Risk of psychological harm and retraumatisation, if sensitive topics are not carefully moderated.
   - Use of generation-sensitive language.
9. **Survivors of natural disasters:**
   - Ongoing trauma or grief, necessitating trauma-informed approaches.
   - Possible instability in housing, employment, or documentation, making follow-up and data protection challenging.
   - Need for rapid referral mechanisms if signs of distress are observed.

The core target groups of PVS at each pilot site will be officially defined by June 2026 (M18) and will be presented in detail in *D3.1 Report on mental health ecosystem profiles of pilot sites*. Thus, this section is going to be updated with the updated information in the next version of this deliverable, namely *D10.3 Regulatory, societal, ethical and gender issues plan - v2.*

Regarding the mental health aspect, in the broader research activities of EQUICARES, particularly within WP1, the project examines specific mental health disorders—including anxiety disorders, mood disorders, trauma-related disorders (e.g., PTSD), eating disorders, and others—to map barriers to care and identify disparities in mental health service access among PVS. These conditions serve to understand how systemic, social, and economic factors contribute to mental health inequalities. However, this research does not involve direct clinical intervention or recruitment of diagnosed populations; rather, it informs the design of inclusive, needs-based solutions within the project.

[4] In EQUICARES, 'youth' is understood as individuals aged approximately 12 to 25 years old, following the perspective promoted by the International Association for Youth Mental Health (IAYMH), which recognizes this extended developmental period as critical for mental health promotion and early intervention.

At the same time, the EQUICARES clinical study does not aim to recruit individuals with diagnosed mental health disorders. Instead, it focuses on PVS who may be at risk of experiencing psychological distress. Individuals with mild or moderate symptoms of common conditions such as anxiety, depression, or insomnia may be included as they will not be systematically excluded, but participants with formal *diagnoses* of these disorders are not *targeted*. However, the study explicitly excludes those with severe mental health disorders—such as schizophrenia, bipolar disorder, psychotic depression, and dementia—to ensure participant safety and ethical compliance. The emphasis is on preventive, community-based mental health support rather than clinical treatment of diagnosed psychiatric conditions.

2.3 Research and pilot design and implementation

2.3.1 Research and intervention activities involving PVS

The main research activities that involve data collection with human participants from vulnerable populations and/or personal data, and interventions, including the methodologies employed, are presented below.

WP1: Setting the assessment framework for the accessibility of mental health and care services and offering data on accessibility barriers at macro-, meso-, and micro-level by people in vulnerable situations

- **Task 1.4**: Performs a large-scale survey targeting citizens (≥200 per pilot), including PVS. D1.4 due in M16 - April 2026.
- **Task 1.5**: Conducts (a) a paper-based on-site survey (questionnaire adapted from T1.4), capturing responses (at least 20) from PVS to capture the contextual and place-based barriers to equal access to mental health and care services, and (b) observational fieldwork with a specific community of PVS will be selected for observational fieldwork, capturing behaviours, social norms, and day-to-day interactions to mental health services (e.g., public hospitals, community-based services). D1.5 due in M16 – April 2026.

WP3: Creation of Smart Health Labs: empowering people in vulnerable situation

- **Task 3.2**: **Multi-actor engagement in Smart Health Labs and deployment of awareness raising campaigns:**
  - Organizes (a) co-creation workshops in each pilot site (>15 people per pilot) to co-define the structure, mission, and governance framework of their local lab, and (b) warm-up events to raise awareness and support the initial engagement in the Smart Health Labs. D3.2 due in M22 - October 2026.
- **Task 3.3**: **Capacity building to enhance health and digital literacy of PVS, service providers, mental care workers and decision makers through MOOCs and workshops:**
  (a) Co-designs a pan-European MOOC programme that includes short courses on digital health and mental health literacy, targeting both PVS (integration of subtitles in pilot and minority local languages will be ensured where necessary) but also service providers, health workers (to equip them with cultural competence, ability to counter bias, etc.) as well as policy makers (e.g. how to interpret data, inclusive data collection) (b) Organizes 3 capacity building workshops to empower PVS as well as other relevant actors. D3.3 due in M36 - December 2027.
- **Task 3.4: Capacity building through community-centric approaches:**

- Under T3.4, SEERC, with the support by Q-PLAN, will coordinate pilot partners to design and implement one small scale Citizen Science project on mental care in the pilot local areas (>10 participants per pilot). D3.3 due in M36 - December 2027.

- **Task 3.5: Development and operation of AI-based Assistant for personalised mental health support**
  - SQUAR will offer the prototype of the Assistant, which will be piloted (pilot clinical study) within the 8 Labs engaging ≥10 participants per pilot.D3.4 due in M22 – October 2026 & D3.5 due in M36 - December 2027.

WP4: Co-design and piloting of innovative solutions for improving access to mental health and care services

- **Task 4.1: Co-creation of deployment roadmaps towards accessible mental health and care services and innovative solutions prototyping:**
  - Organise 1 consultation workshop (≥ 20 participants per workshop, including PVS and relevant stakeholders) to gather local stakeholders and help them design a new (or adapt an existing) solution for enhancing mental health services' accessibility by using principles from social economy and user innovation**.** D4.1 due in M22 - October 2026.
- **Task 4.3: Piloting of innovative solutions (M20-M36):**
  - The roll out of the interventions will be supported by the Smart Health Labs that will ensure the participation of end-users, with a focus on PVS, targeting a minimum pool of 30 participants per pilot. D4.3 due in M36 - December 2027.

To ensure these research and intervention activities are conducted ethically and responsibly, special attention will be given to the ethical implications of engaging with PVS across diverse local contexts. The implementation of each task will be guided by the ethical principles, procedures, and safeguards detailed in the following sections of this handbook.

2.3.2 Ethical considerations of research and intervention activities involving PVS

EQUICARES targets a wide range of PVS including LGBTQIA+ individuals, people with physical and intellectual disabilities, refugees, migrants, ethnoreligious minorities, Roma communities, older adults (including women and migrants), unaccompanied minors, and survivors of natural disasters. These groups often face compounded barriers in accessing mental health services, requiring the project to adopt a high ethical standard of care and protection.

Duty of Care and Participant Safety: EQUICARES is firmly committed to prioritizing the safety, dignity, and well-being of all research participants, particularly PVS. Beyond mitigating risks of retraumatization or unintended harm, the project recognizes an active duty of care to proactively ensure participant safety at all times. Given the nature of the research, particularly in the mental health domain, all researchers and pilot partners must be prepared to respond appropriately, ensuring access to immediate support, safeguarding measures, and referral pathways where necessary. Upholding participant safety is a non-negotiable ethical responsibility and is embedded throughout all stages of research design, implementation, and reporting.

Besides these considerations specific to each target PVS presented at the previous section, there are also some cross-cutting ethical considerations for all PVS, which are:

- **Intersectionality**: many individuals may have multiple vulnerability factors (e.g. age, ethnicity, gender, migrant status), which may lead to complex inequalities, risks and needs.
- **Community engagement and empowerment**: involving PVS not just as research participants, but as co-creators is key to ethical research.
- **Sensitivity to power imbalances and histories of marginalisation**, requiring respectful and inclusive methods of engagement and data collection.
- **Ensuring voluntary, informed participation** in contexts where the capacity to consent may be challenged by legal, linguistic, psychological, or cultural barriers, considering also legal tutors whenever needed.
- **Special attention to the mental health vulnerabilities of participant**s, given the project's focus on mental health problems such as anxiety, mood disorders, trauma-related conditions, and disruptive behaviours. This requires special consideration to data confidentiality and management.
- **The need for contextual adaptations in engagement strategies and methods to collect data** to reflect local needs and cultural norms.
- **Ethical AI development**: ensuring that the development of the AI-based assistant do not reproduce bias against any of these groups[5].
- **Preventing unintended harm or retraumatisation** during data collection, observational fieldwork, and AI-based interactions.
- **Mitigating potential issues of cultural competence and trust** by incorporating translators, cultural experts, and other specialists into the process.

At the time of writing of this report (M4), the intervention activities, including the AI assistant pilot clinical study, that will take place are not yet fully defined. Part of the interventions/solutions that will be deployed in each Smart Health Lab will stem from co-creation methodologies and will be defined as part of the work conducted under WP3 and WP4. Those will inform the ethical considerations defined in the next version of the deliverable (D10.3 in M24).

2.3.3 Ethical guidelines for engaging with PVS

In the context of EQUICARES, where research and intervention activities directly involve PVS, and touch upon sensitive data (e.g., mental health issues, ethnicity, gender identity), it is essential to have clear and ethically sound procedures for engaging with them. In particular, EQUICARES partners have to ensure that the participation of PVS will follow processes that are:

1. **Gender-affirming**: recognize, respect and support a person's self-identified gender identity and expression.
2. **Trauma-informed**: recognize the impact of trauma on individuals and prioritise safety, trust and empowerment to avoid re-traumatization in research and interventions.
3. **Culturally sensitive**: taking into account social norms and beliefs and stigma that may affect participation.
4. **Language-accessible and literacy-appropriate**: project materials and tools will be adapted to different literacy levels and translated into local and minority languages.
5. **Inclusive**: ensure that all individuals, regardless of their age, background and abilities, can participate meaningfully, equitably, and with dignity in research and co-creation.

[5] More detail on the AI-based assistant is provided in Section 4.

6. **Aware of intersectionality:** ensure that the overlapping identities and experiences of individuals, such as gender, ethnicity, disability, or age, are recognised and addressed, preventing compounded forms of exclusion or discrimination.
7. **Considering potential economic disparities** when organizing activities to ensure they are accessible to PVS, including choosing easily reachable locations and scheduling outside of standard working hours.

In all pilot cases where primary research will take place, a **clear protocol** will be designed by academic partners with the assistance of pilot partners, to present criteria and guidelines on the participation of PVS in research. These protocols will be submitted together with all the relevant material for ethical approval from the relevant authorizing bodies[6]. These criteria will be applied later on during the engagement actions under Smart Health Labs.

Mitigation mechanisms will be put in place, including examples like the possibility of a core family member to sign on behalf of participants and accept liability; the external engagement of experts in sign language; or the external engagement of local translators to assist participants in vulnerable situations. In addition, our **communication strategy** will integrate easy-to-read and easy-to-understand tools to ensure accessibility for participants with disabilities, people with low educational backgrounds, those facing language barriers, or individuals with low literacy. **Such strategies and tools will be context-dependent**, in line with previous studies that highlight that the engagement, recruitment and retainment of PVS in health research activities should **always consider local specificities and needs**.

The next sections briefly present how these principles can be applied in the EQUICARES practices.

2.2.3.1. Gender-affirming practices

In EQUICARES, gender-affirming practices are integral to ensuring that all individuals, particularly transgender, non-binary and gender-diverse participants, are treated with dignity, respect and recognition of their self-identified gender. These practices include actions, policies or approaches that respect, support and validate a person's gender identity and expression, especially when it differs from the sex they were assigned at birth. They are especially important in mental health and care interventions, where people often face compounded barriers due to gender identity.

Some indicative examples of gender-affirming practices are presented below:

- Using inclusive and self-identifying genders beyond 'male' and 'female' in surveys, interviews and digital tools, e.g. non-binary, trans, prefer to self-describe (EIGE, 2016).
- Asking for pronouns and allowing self-identification rather than assuming gender based on appearance or name (APA, 2015).
- Providing access to gender-affirming care, such as psychosocial support, in line with international standards (WPATH, 2022; WHO, 2022).
- Ensuring that staff are trained in communication that includes all genders.
- Avoiding pathologizing language and respecting bodily autonomy.
- Using neutral or affirming language in written and verbal communication (EIGE, 2016).
- Avoiding assumptions about someone's body, identity, or experiences based on their gender.

[6] More information on the ethical governance and oversight, as well as the relevant ethical approval processes, is provided in Section 5.

These practices are not only ethical, but also prove to improve health outcomes and participation among gender-diverse individuals. The World Health Organization emphasizes that a gender-affirming environment promotes well-being and reduces barriers to accessing care and services (WHO, 2022). The WPATH standards of care (version 8) serve as a global benchmark for the design of health services that meet the needs of transgender and gender-diverse individuals (WPATH, 2022).

Within EQUICARES, all communication, research activities, engagement strategies and pilot interventions will integrate these principles to ensure that gender-diverse participants feel recognized, respected and safe.

2.2.3.2. Trauma-informed practices

Trauma-informed practices are an essential ethical approach in research and healthcare involving individuals who may have experienced trauma, including (but not limited to) refugees, asylum seekers, unaccompanied children, as well as survivors of natural disasters. Trauma-informed care recognizes the widespread impact of trauma on mental, physical and emotional health and aims to create environments that promote safety, empowerment, and healing rather than traumatization.

In the European context, trauma-informed principles are increasingly embedded in human rights and care-based policies. The EU Agency for Fundamental Rights (FRA) has explicitly recommended trauma-sensitive support systems for victims of crime, emphasizing respectful treatment, access to psychosocial services, and awareness of trauma among service providers (FRA, 2020). Similarly, the Council of Europe's Istanbul Convention on preventing violence against women and domestic violence (2011) urges Member States to adopt trauma-informed practices in protection services, ensuring that survivors are treated with compassion, confidentiality, and agency.

EQUICARES aligns with this framework by embedding trauma-informed practices into its research and pilot interventions, particularly in:

- Interviews and observational fieldwork with populations affected by displacement or conflict.
- Pilot interventions in the Smart Health Labs involving individuals or communities with trauma histories.

The AI-based assistant must always act with user safety and dignity as its highest priority. Any indications of distress, crisis, or harm must trigger immediate escalation to human support channels. Some indicative practices also include:

- Clearly explaining participation procedures and allowing participants to pause or withdraw at any time.
- Providing a clear referral process for incidental findings (see section below) to trusted local mental health services.
- Training staff and researchers on recognizing signs of trauma and responding appropriately.
- Using accessible, non-stigmatizing, and culturally sensitive language.

By adopting this trauma-informed approach, EQUICARES reinforces its commitment to ethical and inclusive mental health research and interventions.

2.2.3.3. Culturally sensitive practices

Culturally sensitive processes recognise and respect the diverse cultural backgrounds, beliefs and lived experiences of participants. Since EQUICARES engages with individuals from Roma

communities, migrant and refugee populations, as well as other ethnoreligious groups, cultural sensitivity is essential to ensure ethical and inclusive engagement.

Cultural sensitivity begins with an awareness that culture shapes how people perceive mental health, help-seeking and participation in research. Researchers and facilitators (e.g. cultural mediators) must approach all interactions with openness, humility, and a willingness to learn from participants. This includes avoiding stereotypes, respecting traditions and values, and being aware of potential stigma or mistrust related to health systems, especially among historically marginalized groups.

In EQUICARES, culturally sensitive processes include:

- Using appropriate language and avoiding medical, legal or other academic jargon.
- Adapting communication styles to local norms (e.g. using indirect or formal language where appropriate).
- Respecting religious or social customs, such as gender separation in group discussions or prayer times.
- Being attentive to non-verbal cues that may signal discomfort or disengagement.
- Involving cultural mediators or interpreters in community engagement.
- Holding sessions in familiar, trusted community spaces rather than formal institutions.

Importantly, cultural sensitivity is not static; it requires continuous reflection, listening and adaptation, especially in transnational projects like EQUICARES, where 'culture' intersects with gender, age, ethnicity and socioeconomic status. The ultimate goal is to foster environments of mutual respect, where participants who are PVS feel seen, heard and valued, regardless of their background. Culturally sensitive approaches are supported by EU guidance (e.g. ECDC and FRA) and serve as a foundation for building culturally competent systems[7] that go beyond awareness towards structural inclusion.

2.2.3.4. Language-accessible and literacy-appropriate communication

Effective communication is a cornerstone of ethical, inclusive engagement, particularly when working with linguistically diverse or low-literacy populations. EQUICARES engages individuals from migrant backgrounds, Roma communities, refugees, and elderly participants who may have limited proficiency in the dominant language, or who may have lower levels of formal education.

To ensure equitable participation, EQUICARES commits to language-accessible and literacy-appropriate communication across all research and intervention activities. This includes:

- Translating material into local and minority languages.
- Using simple and plain language, free of technical jargon.
- Integrating visual aids, symbols or illustrations to support comprehension.
- Providing, where needed, live interpretation, audio narration, or community translators during data collection or workshops.
- Offering audio narration or simplified versions of documents for people with low literacy.
- Using interactive methods like storytelling or games in capacity-building sessions.

[7] Culturally competent systems are organisations or services that are intentionally designed to recognise, respect, and respond effectively to cultural diversity at every level — from policies and staff training to service delivery and community engagement. They go beyond individual awareness to ensure that structures, processes, and outcomes are inclusive and equitable for people from all cultural backgrounds.

Informed consent procedures must be adapted to ensure participants fully understand the purpose, risks and rights associated with participation. This may involve reading materials aloud, using diagrams, or validating understanding through conversation rather than formal literacy checks. Moreover, digital tools, including the AI-based assistant, should offer multi-language and audio accessibility features, especially for those with visual impairments or low literacy. These practices not only promote inclusion but also enhance data quality and participant trust.

Language and literacy-sensitive approaches are supported by the Council of Europe's Framework Convention for the Protection of National Minorities and the UNESCO Recommendation on Multilingualism (see Section 3. Ethical and regulatory framework).

2.2.3.5. Inclusive practices for physical, intellectual disability, youth, and older adults

EQUICARES engages a wide range of participants, including people with physical and intellectual disabilities, young people (including unaccompanied minors), and older adults. Each of these groups faces distinct barriers to participation and requires tailored, ethically sound approaches that promote dignity, autonomy, and accessibility. Inclusive practices ensure that research, interventions, and digital tools are equitable and responsive to these needs.

Inclusive practices within EQUICARES embrace the principle of **Universal Design**, which promotes the creation of products, environments, programmes, and services that are accessible and usable by all people, to the greatest extent possible, without the need for specialized adaptations. As defined in Article 2 of the United Nations Convention on the Rights of Persons with Disabilities (CRPD)[8], Universal Design aims to ensure accessibility for all, while acknowledging that specific assistive devices may still be necessary for some individuals. This approach fosters greater **equity, safety, comfort, social inclusion**, and contributes to the **economic viability** and **quality of life** of diverse populations, including persons with disabilities, youth, and older adults. Universal Design does not only benefit those with disabilities but enhances usability for everyone, reinforcing the project's commitment to creating inclusive and human-centered innovations.

1. **Disability-inclusive practices:**

In line with the UN Convention on the Rights of Persons with Disabilities (CRPD) and the EU Strategy for the Rights of Persons with Disabilities (2021-2030), EQUICARES promotes:

- Using accessible formats tailored to the specific needs of individuals and communities (indicative examples: large print, subtitles, sign language, easy-to-read documents).
- Adapted informed consent procedures and assistive technologies.
- Avoiding medicalising language as well as technical European jargon and focusing on barrier-free participation.
- Involving people with disabilities not only as participants but also in co-design and decision-making, e.g. regarding the governance of Smart Health Labs.

2. **Youth-friendly practices:**

In line with the EU Youth Strategy (2019-2027), and guided by WHO Global Standards for Adolescent Health Services (see Section 3 on Ethical and regulatory frameworks), EQUICARES applies:

- Non-judgmental, safe space for engagement.
- Clear, age-appropriate communication and flexible participation formats.
- Appropriate assent and consent procedures in line with legal and ethical standards.

[8] United Nations. (2006). Convention on the Rights of Persons with Disabilities. Article 2. Available here.

- Inclusion of youth as active contributors, not just research subjects.

3. **Older age-sensitive practices:**

Aligned with the Council of Europe Recommendation CM/Rec(2014)2 on the rights of older persons, EQUICARES ensures:

- Age-appropriate communication (plain language, large fonts, clear spacing).
- Respect for autonomy and sensitivity to cognitive or mobility limitations.
- Accessible spaces and tools, with patient and supportive facilitation.
- Recognition of the diversity of older adults, avoiding stereotypes or assumptions.

Altogether, these inclusive practices contribute to an ethical, human-rights-based approach that fosters meaningful participation and protects the dignity of all involved, regardless of their age and physical abilities.

2.2.3.6. Intersectional Inclusion Framework

Intersectionality refers to how different forms of inequality, based on factors such as gender, ethnicity, age, disability, sexual orientation, socioeconomic status, etc., interact and compound. The EQUICARES intersectional inclusion framework ensures that individuals with multiple vulnerabilities are not treated as isolated categories but as people experiencing overlapping systems of disadvantage. For example, a Roma woman with a disability or an trans refugee who is of older age may face unique barriers in accessing care and participating in research. Intersectional inclusion recognises that standard approaches may not address the combined impact of these experiences.

Practically, this means EQUICARES:

- Collects **disaggregated data** to identify patterns of exclusion.
- Designs **inclusive tools and spaces** with flexibility to accommodate diverse experiences.
- Ensures that engagement is not tokenistic, but participatory, contextual, and empowering.

Ethically, intersectional frameworks challenge one-size-fits-all models and encourage researchers to reflect on their own positionality and assumptions. This also applies to AI development: the AI-based Assistant must be trained and tested with a diversity of users, using inclusive language and avoiding reinforcing stereotypes or biases. The European Institute for Gender Equality (EIGE) promotes intersectionality in policymaking, particularly in gender equality and social inclusion. EQUICARES builds on this by embedding intersectionality into research design, co-creation processes, and policy outputs, ensuring that no one is left behind, especially those at the margins of multiple systems.

2.3.4 Protocol for incidental findings and referrals

In the context of EQUICARES research and intervention activities, it is also essential to have clear and ethical sound protocols for managing incidental findings, referring to unexpected observations that may indicate a participant is in psychological distress or in need of immediate support. These protocols are designed to protect participants, ensure continuity of care, and uphold the ethical principle of beneficence (do good) and non-maleficence (do no harm). Examples of incidental findings may include indications of suicidal ideation or intent, undisclosed trauma or abuse, severe distress or panic attack, symptoms requiring assessment by a health professional.

The following steps will be followed:

1. Predefined response plan before fieldwork or data collection:

   a. Each pilot partner, with support from academic and ethics teams, will define a clear escalation pathway for handling different types of incidental findings.
   b. Designated local focal points or professionals for referral (e.g. social workers, psychologists, healthcare staff) will be identified in advance.
2. Ethical compliance of researchers and pilot organizations' staff:
   a. All personnel involved in data collection and community engagement will adhere to the ethical principles and guidelines for engaging with PVS, recognizing verbal and behavioural cues, responding empathetically and without judgement, and activating the response protocol.
   b. If the AI-based assistant detects keywords or patterns suggestive of distress, a referral suggestion or help-seeking prompt will be offered.
3. Immediate response:
   a. If a participant appears at risk during a session (e.g. discloses suicidal thoughts), the researcher or facilitator should
      i. Gently pause the activity
      ii. Follow the site-specific referral or support plan
4. Referral to support services
   a. Each pilot partner will maintain a directory of trusted support services, including mental health professionals, emergency services, shelters or legal aid (as applicable).
   b. Where appropriate, warm referrals[9] may be made with the participant's consent.
5. Documentation and follow-up
   a. A minimal and secure record of the incident will be kept (without unnecessary personal details) in accordance with the Data Management Plan (DMP). The relevant template is provided in the Annexes (Incidental Findings Log Template p. 73).
   b. The Ethics Committee[10] may review these cases as part of the ethics monitoring process.

These procedures are not only fundamental for safeguarding participants, but also for reinforcing the project's ethical commitment to **equity, dignity, and rights-based research**. They complement the data management and privacy protections outlined in D9.2 Data Management Plan and ensure that EQUICARES meets the highest ethical standards in all contexts involving PVS.

📌 **Remember: Participant Safety First**

At every stage of engagement with participants, especially those in vulnerable situations, the foremost priority is **ensuring their safety, dignity, and well-being**. If a participant discloses distress, harm, or risk, researchers must act immediately according to the agreed referral and safeguarding protocols. Protecting participants is not just about preventing harm; it is an active, ongoing responsibility embedded in the ethical foundations of EQUICARES.

[9] **Warm referrals** are a supportive way of connecting someone to another service by personally facilitating the handover, rather than just providing contact information or instructions (as in a "cold referral"). For EQUICARES, warm referrals might be used when a participant shows signs of distress during a study, and a researcher helps them access local mental health or social services, especially important for vulnerable groups like refugees, minors, or people with disabilities.

[10] More information on the composition of the team, as well as roles and responsibilities is provided in Section 5.

3. Ethical and regulatory framework

3.1 International and EU policies

3.1.1 Mental health and clinical practice

Table 3.International and EU policies on mental health and clinical practice.

What	Applicable since	Description	Binding
UN Convention on the Rights of Persons with Disabilities (CRPD)	2008	First international treaty on disability rights, covering physical and mental disabilities. Adopts a human-rights approach to disability, requiring equal rights and non-discrimination for persons with disabilities in all areas of life. It affirms access to healthcare (including mental health care), independent living, and freedom from abusive treatment. The EU is a party to the CRPD. The CRPD is especially relevant to mental health ethics, as it demands a shift to person-centered, rights-respecting support for individuals with psychosocial disabilities (mental health conditions).	**Yes**
EU Union of equality: Strategy for the Rights of Persons with Disabilities (2021–2030)	2021	The EU Strategy for the Rights of Persons with Disabilities 2021–2030 is the European Union's comprehensive roadmap for advancing the rights, inclusion, and participation of people with disabilities. It builds on the implementation of the UN Convention on the Rights of Persons with Disabilities (CRPD), which the EU and all its Member States have ratified.	No
WHO Comprehensive Mental Health Action Plan **2013–2030**	2013	Global action plan adopted by the World Health Assembly in 2013 (extended to 2030 in 2019) to guide countries in improving mental health. It sets out targets and strategies to promote mental well-being, prevent mental disorders, provide community-based mental health services, and protect human rights of people with mental health conditions. Though not a treaty, it is a key framework aligning mental health policies with human rights standards.	No
Council of Europe Convention on Human Rights and Biomedicine (Oviedo Convention)	1999	The only international legally binding instrument on biomedical ethics. It establishes fundamental patient rights in healthcare, including the requirement of free and informed consent to medical interventions. It specifically addresses mental health care by setting conditions for involuntary	**Yes**

		treatment of persons with mental illness, aiming to protect their dignity and rights. This convention provides a European framework for ethical mental health practice in line with human rights.	
WHO Global Standards for Quality Health-Care Services for Adolescents	2015	The WHO Global Standards for Quality Health-Care Services for Adolescents (2015) provide a comprehensive framework to ensure that health services for adolescents are equitable, acceptable, appropriate, and effective. They emphasise confidentiality, age-appropriate care, youth participation, and non-discrimination, aiming to make health systems more responsive to the specific needs and rights of young people.	No
World Medical Association (WMA) Declaration of Helsinki – Ethical Principles for Medical Research Involving Human Subjects	1964 (adopted); latest revision 2024	Issued by the World Medical Association, this is one of the most influential set of ethical guidelines for medical and psychological research involving human participants. It outlines principles such as informed consent, risk-benefit assessment, protection of vulnerable groups, and the need for ethical review. While not legally binding, it is considered international ethical best practice and widely incorporated into national and institutional ethics frameworks.	No
European Commission Communication: "A comprehensive approach to mental health"	2023	A recent EU policy initiative (adopted 7 June 2023) outlining a cross-sectoral strategy to put mental health on par with physical health. It includes 20 flagship initiatives backed by €1.23 billion to support Member States in prevention, destigmatization, and improving access to mental health care. While not law, this framework guides EU countries and stakeholders in coordinated action on mental health and embeds mental well-being in policies like education, employment, and digitalization.	No
APA. Guidelines for Psychological Practice with Transgender and Gender Nonconforming People.	2015	Offers 16 guidelines for ethical, inclusive, and affirming psychological care for TGNC individuals. Relevant for EQUICARES in supporting gender-diverse participants and ensuring inclusive mental health services.	No
EU Medical Device Regulation (MDR) 2017/745	into force in May 2017 and fully applicable in May 2021	The EU Medical Device Regulation (MDR) 2017/745 is the core legislative framework governing the safety, performance, and marketing of medical devices within the European Union. It entered into force in May 2017 and became fully applicable on 26 May 2021, replacing the previous Medical Devices Directive (93/42/EEC) and the Active Implantable Medical Devices Directive (90/385/EEC). The MDR significantly strengthens the regulatory requirements for medical devices, introducing stricter clinical evaluation, enhanced post-market surveillance, transparency through the European	**Yes**

		Database on Medical Devices (EUDAMED) database[11], and clear classification rules. It applies to a wide range of products, including software and AI tools with medical purposes[12].	
EU Regulation 536/2014 on Clinical trials on medicinal products for human use	2014 (effective as of 2022)	The Regulation (EU) No 536/2014 establishes harmonised rules for conducting clinical trials on medicinal products involving human participants across the EU. It ensures high standards of safety, transparency, and informed consent, and mandates centralised trial registration and reporting, strengthening participant protection and ethical oversight in health-related research.	**Yes**
International Conference on Harmonisation (ICH) Guidelines for Good Clinical Practice (GCP)	1996 (Rev. 3 in 2025)	The ICH Good Clinical Practice (GCP) guidelines provide an international ethical and scientific standard for designing and conducting research involving human participants. They ensure informed consent, ethical oversight, data integrity, and participant safety, making them relevant to EQUICARES for health-related research and pilot interventions with vulnerable populations.	No
The Belmont Report	1979	The Belmont Report is a foundational document in research ethics that outlines three core principles: Respect for Persons, Beneficence, and Justice. Although developed in the U.S., it has shaped ethical research practices globally and complements EU frameworks such as the Declaration of Helsinki and GDPR. In EQUICARES, its principles are particularly relevant for safeguarding the rights and well-being of participants from vulnerable groups, ensuring informed consent, equitable participation, and the responsible management of risks and benefits in all research and intervention activities.	No

3.1.2 Inclusion and protection of People in Vulnerable Situations (PVS)

Table 4.International and EU policies on inclusion and protection of PVS.

What	Applicable since	Description	Binding
EU Charter of Fundamental Rights	2009	Legally binding on EU institutions and Member States when implementing EU law. It protects civil, political, and social rights, including non-discrimination (Art. 21), rights of the elderly (Art. 25),	**Yes**

[11] EUDAMED is a central European database developed by the European Commission to improve transparency, traceability, and coordination in the regulation of medical devices under the EU Medical Device Regulation (MDR) and the In Vitro Diagnostic Medical Devices Regulation (IVDR).

[12] For EQUICARES, if the AI-based Assistant is considered a medical device (e.g. if used for diagnosis or therapeutic advice), it must comply with MDR requirements for safety, data integrity, and human oversight. However, this is still open for discussion and will be clearly defined in the next version of the deliverable (D10.3).

		integration of persons with disabilities (Art. 26), rights of the child (Art. 24), and health care access (Art. 35). Also guarantees data protection (Art. 8), relevant to AI tools used in EQUICARES.	
Council of Europe, European Convention on Human Rights (ECHR)	1953	Adopted by the Council of Europe, the ECHR is a cornerstone of human rights protection in Europe. It guarantees the right to life (Art. 2), prohibition of inhuman or degrading treatment (Art. 3), and the right to privacy (Art. 8) — all key for mental health ethics and the protection of vulnerable groups.	**Yes**
Council of Europe, European Social Charter (Revised)	1999 (revised charter in force)	Council of Europe treaty guaranteeing economic and social rights, complementing the civil-political rights of the ECHR. It establishes the right to health and medical assistance for everyone, which implicitly includes mental health care access. States must ensure adequate healthcare facilities, prevention, and social services. The Charter also protects rights of people with disabilities and elderly, obliging inclusive policies. This creates a binding standard for mental health support as part of broader social rights.	**Yes**
EU Youth Strategy (2019–2027)	2019	The EU Youth Strategy (2019–2027) promotes the engagement, empowerment, and inclusion of young people across the EU, with a strong focus on mental health, equality, and active participation in democratic life. It encourages cross-sector collaboration and highlights the importance of supporting vulnerable and marginalised youth, including through education, digital tools, and innovation.	No
UN Universal Declaration of Human Rights (UDHR)	1948	The UN Universal Declaration of Human Rights (1948) affirms the inherent dignity, equality, and rights of all people. It promotes non-discrimination, privacy, freedom of expression, and the right to participate in science and cultural life—principles that guide EQUICARES in ensuring ethical and inclusive research with vulnerable populations.	No
UN Convention on the Rights of the Child (CRC)	1990 (entry into force)	Most widely-ratified human rights treaty, covering all children under 18. It preserves the right to protection, education, health care, and an adequate standard of living for children. Key principles include the best interests of the child, non-discrimination, survival and development, and child participation in decisions. The CRC obliges states to protect especially vulnerable minors (e.g. unaccompanied children, refugee children) and to prevent abuse, exploitation, and neglect.	**Yes**
UN International Convention on the Elimination of All Forms of Racial Discrimination (ICERD)	1969 (entry into force)	The UN's first dedicated human rights treaty to combat racism. It commits states to outlaw racial discrimination in law and practice and promote understanding among all races. Parties must prohibit and criminalize hate speech and racist violence, ensure equal access to opportunities (education, employment, housing) regardless of ethnicity, and provide remedies for victims of discrimination. This convention protects ethnoreligious minorities (including Roma) from discrimination and is monitored by the CERD Committee.	**Yes**
UN Convention relating to the Status	1954 (Protocol in 1967)	The cornerstone of international refugee protection. It defines who is a "refugee" and the obligations of states toward them, including the critical principle of non-refoulement (no forced return to persecution). The Convention guarantees refugees rights to non-discrimination, identity papers, work,	**Yes**

of Refugees (1951) + 1967 Protocol		education, public relief, and courts access. Refugees are acknowledged as extremely vulnerable, lacking national protection and the Convention (with the 1967 Protocol removing temporal/geographic limits) aims to ensure their safety and dignity in host countries.	
Council of Europe, Framework Convention for the Protection of National Minorities (FCNM)	1998	A multilateral European treaty dedicated to minority rights protection. It requires states to combat discrimination against national minorities, preserve their cultures and languages, and promote their equal participation in public life. For groups like Roma, religious or linguistic minorities, the FCNM sets standards on education in mother tongue, media access, use of minority languages, and consultation of minority communities. It is legally binding on European states and monitored by an advisory committee.	**Yes**
UNESCO Recommendation on the Promotion and Use of Multilingualism and Universal Access to Cyberspace	2003	This recommendation encourages linguistic diversity and equal access to digital resources across languages. Relevant to EQUICARES for ensuring multilingual communication in AI tools and research.	No
EU Gender Equality Strategy 2020–2025	2020	Outlines the EU's commitment to achieving a gender-equal Europe by addressing gender-based violence, closing gender gaps, and promoting gender mainstreaming across all EU policies. For EQUICARES, it supports the integration of gender analysis, especially in designing inclusive services for women in vulnerable groups (e.g. Roma, elderly, migrant women).	No
EU Roma Strategic Framework for Equality, Inclusion and Participation (2020–2030)	2020	Builds on the previous EU Roma framework and introduces stronger targets on combating antigypsyism, promoting equality, and increasing the participation of Roma communities. It addresses intersectionality (gender, age, disability) and is highly relevant for EQUICARES pilots involving Roma populations.	No
EU LGBTIQ Equality Strategy 2020–2025	2020	The EU's first strategy focused specifically on protecting the rights of LGBTQIA+ people. It addresses discrimination, safety, and access to services, and promotes inclusion across all sectors. For EQUICARES, it offers essential guidance to ensure the AI Assistant and project activities are inclusive of LGBTQIA+ users and communities.	No
Council of Europe Recommendation CM/Rec(2014) 2 on the Human Rights of Older Persons	2014	A comprehensive recommendation urging member states to ensure the dignity, autonomy, and inclusion of older persons. It calls for access to quality care, protection from abuse, and participation in public life.	No

EC Recommendations for Integrated Child Protection Systems	2015	These guidelines provide an EU framework for child-centred, trauma-informed, and rights-based protection systems. Relevant to EQUICARES for engaging youth and unaccompanied minors ethically.	No
UN Madrid International Plan of Action on Ageing (MIPAA)	2002	A global non-binding framework promoting the rights and well-being of older persons through active ageing, healthcare access, and social participation. Adopted by 159 countries. It promotes goals for equitable, age-sensitive care and digital health services.	No
WPATH. (2022). Standards of Care for the Health of Transgender and Gender Diverse People**, Version 8.**	2022	Comprehensive clinical and ethical guidance for delivering gender-affirming care. It covers mental health, medical transition, social inclusion, and rights-based practices. Relevant to EQUICARES in ensuring safe, inclusive engagement with LGBTQIA+ participants, especially in digital health tools and community-based care.	No
World Bank Group Gender Strategy 2024 – 2030	2024	The WBG Gender Strategy 2024-30 puts forward the bold ambition to accelerate gender equality to end poverty on a livable planet in alignment with the World Bank Group Evolution Roadmap. The strategy responds to the global urgency, fundamentality, and complexity of achieving gender equality. Building on implementation of the WBG Gender Strategy 2016-23, the new strategy engages with greater ambition – approaching gender equality for all as essential for global development – and engages differently. The WBG Gender Strategy 2024-30 focuses on concerted action, financing, and programs at scale to support foundational wellbeing, economic participation and women's leadership. This will contribute to i) progress in ending all forms of gender-based violence, ii) stronger and more resilient human capital, iii) more and better jobs, including jobs of the future, iv) greater ownership and use of economic assets, v) wider access to and use of enabling services, vi) advances in women's participation in decision-making.	No

3.1.3 Data, Artificial Intelligence and Cybersecurity

Table 5.International and EU policies on data, AI and Cybersecurity.

What	Applicable since	Description	Binding
EU General Data Protection Regulation (GDPR, 2016/679)	2018	The General Data Protection Regulation (GDPR) is the EU's landmark privacy law setting a high-standard, comprehensive framework for personal data protection. It is designed to ensure the rights and freedoms of individuals whose data is being processed. It establishes clear guidelines for how personal data should be handled, with an emphasis	**Yes**

		on transparency, accountability, and security. The regulation aims to safeguard individuals from unauthorized use of their data while empowering them with rights to control how their personal information is collected, stored, and shared.	
Council of Europe, Convention 108 (Convention for the Protection of Individuals regarding Automatic Processing of Personal Data)	1985	The first and (until recently) only international treaty on data protection. Convention 108 requires signatory countries (including EU states and others) to enact domestic laws respecting fundamental privacy principles – such as fair and lawful data collection, data quality, purpose specification, and individuals' rights to access and correct their data. An Amending Protocol (Convention 108+, 2018) modernizes it (e.g. adding biometric, genetic data safeguards) and is in the process of ratification. Convention 108 provides a baseline for cross-border data protection and is open globally, fostering convergence of privacy standards.	**Yes**
EU Artificial Intelligence Act (AI Act)	2024, fully enforceable in 2026	The AI Act is the European Union's proposed regulatory framework aimed at ensuring the safe, ethical, and trustworthy development and use of Artificial Intelligence (AI) across the EU. It adopts a risk-based approach, classifying AI systems into categories such as unacceptable risk, high risk, limited risk, and minimal risk, with stricter requirements for high-risk applications. The Act focuses on promoting transparency, accountability, and human oversight while fostering innovation and protecting fundamental rights. It complements existing legislation like the GDPR and is central to shaping the future of AI governance in Europe.	**Yes**
EC - INDEPENDENT HIGH-LEVEL EXPERT GROUP ON AI: Trustworthy AI Assessment List	2019	The Assessment List for Trustworthy AI is the operational tool of the Ethics Guidelines for Trustworthy AI, aiming to ensure that users benefit from Artificial Intelligence (AI) without being exposed to unnecessary risks. This list, first presented with the Ethics Guidelines in June 2019, was revised following a piloting process that involved more than 350 stakeholders.	No
WMA Declaration of Taipei on Ethical Considerations Regarding Health Databases and Biobanks	2016	The WMA Declaration of Taipei (2016) provides ethical principles for the collection, storage, and use of health data and biological material in databases and biobanks. It emphasises informed consent, transparency, data protection, and participant rights, ensuring that secondary uses of data uphold ethical and human rights standards.	No
EU, ENISA Guidelines for Secure Software Development	2020	The ENISA Guidelines for Secure Software Development provide a comprehensive set of best practices endorsed by the EU to ensure software systems are built with **security, privacy, and resilience by design**. They cover areas such as secure coding, threat modelling, access control, data protection, and supply chain security. In EQUICARES, these guidelines support the ethical and secure development of digital tools, including the	No

		AI-based Assistant, by aligning with GDPR principles, minimising cybersecurity risks, and protecting sensitive user data in health-related applications.	

3.1.4 National policies

Each EQUICARES pilot intervention must adhere to national-level policies, including laws, directives, strategic plans and other guiding instruments. A detailed analysis of country-specific requirements is provided below.

2.1.4.1. Ireland

Table 6.Relevant national policies in Ireland.

What	Applicable since	Description	Binding
Sharing the Vision: A Mental Health Policy for Everyone https://www.hse.ie/eng/about/who/mentalhealth/sharing-the-vision/	2020	'Sharing the Vision - A Mental Health Policy for Everyone' is Ireland's national mental health policy. It was published in June 2020. It is a policy framework for the continued development and enhancement of mental health services in Ireland from 2020 to 2030. It replaces the previous policy, 'A Vision for Change'.	No
Sharing the Vision Implementation Plan (Associated with the above) 'Sharing the Vision Implementation Plan 2022 to 2024'	2022	Implementing the recommendations in the policy was a commitment in the last Programme for Government and a priority for the Department of Health and the HSE. The 'Sharing the Vision Implementation Plan 2022 to 2024' provides a high-level description of intended outputs between 2022 to 2024. Further implementation plans are to be developed for 2025 to 2027 and 2028 to 2030.	No
Mental Health Acts **https://revisedacts.lawreform.ie/eli/2001/act/25/revised/en/html**	2001	The Mental Health Acts 2001-2022 (also known as 'the Mental Health Act') is the main law that covers mental health care and treatment in Ireland. It applies to both adults (aged 18 and over) and young people. There are some specific parts of the Act that only apply to young people. The Mental Health Act 2001 sets out the law on how and why you can be admitted to a psychiatric hospital and your rights as a patient. The Government has published the Mental Health Bill 2024. If passed by the Oireachtas, this bill is set to replace the existing Mental Health Acts 2001–2022. and: - Update the process and criteria for involuntary admission and detention for people with severe mental health difficulties - Overhaul the approach to consent to treatment for involuntarily admitted people	Yes

		- Expand the Mental Health Commission's regulatory function to include all community mental health residences and services, including all community Child and Adolescent Mental Health Services (CAMHS) - Strengthen the safeguards for people accessing inpatient treatment - Update the care and treatment of children and young people - Allow 16 and 17-year-olds to consent to or refuse mental health treatment - Further alignment with the principles of the Assisted Decision-Making (Capacity) Acts 2015 and 2022. More info: The law on mental health in Ireland	
Roadmap for Social Inclusion 2020 - 2025: Ambition, Goals and Commitments	2020	Published in January 2020. It is the successor to the National Action Plan for Social Inclusion which concluded at the end of 2017 and is the latest in a series of such plans dating back to 1997. The Roadmap for Social Inclusion is an **overarching statement of Government strategy**, which acknowledges the range of sectoral plans already in place that have social inclusion as a core objective, in areas such as education, health, children and childcare, community development and housing.	No
National LGBTI+ Inclusion Strategy https://www.gov.ie/en/publication/bab0fe-launch-of-the-lgbti-inclusion-strategy-2019-2021/	2019	The National LGBTI+ Inclusion Strategy 2019-2021, published at the time by the Department of Justice and Equality, aims to promote inclusion, protect rights, and improve quality of life and wellbeing for LGBTQIA+ people. The strategy contains over 100 actions to achieve these goals, and funding of almost €1m is available to support equality and LGBTQIA+ initiatives. The Department of Justice and Equality is developing a National Strategy to improve the lives of LGBTQIA+ people in Ireland, with the overall aim of targeting discrimination, promoting inclusion, and improving quality of life and wellbeing for LGBTQIA+people. The Department of Children, Equality, Disability, Integration and Youth is developing a successor strategy to the National LGBTI+ Inclusion Strategy (2019-2021) to promote inclusion, protect rights and to improve quality of life and wellbeing for LGBTQIA+ people; enabling them to participate fully in Ireland's social, economic, cultural, and political life. It is due to be published in 2025. LGBT Ireland (EQUICARES partners) has led the review of the National LGBTI+ Inclusion Strategy with the publication of the shadow report last year. See here.	No
National AI Strategy for Ireland AI - Here for Good: National Artificial Intelligence Strategy for Ireland	2021 (refreshed 2024)	Ireland's National AI Strategy was refreshed in 2024 to take account of the significant developments in AI technology and regulation since the original strategy was published in 2021. Ireland's first National Artificial Intelligence (AI) Strategy, AI - Here for Good: National Artificial Intelligence Strategy for Ireland, was launched in July 2021. This strategy aims to provide a high-level direction to the development, adoption and implementation of AI in Ireland. The National AI Strategy serves as a roadmap for how Ireland can leverage the potential of AI for unlocking productivity, for addressing societal challenges, and for delivering public services. It envisions a future for Ireland as an	No

		international leader in using AI to the benefit of business, public services, and - most importantly - for people, through a people-centred, ethical approach to AI development, adoption and use. The strategy set out a whole of government approach to putting the necessary enablers in place to underpin AI adoption in enterprise and public services, including a supportive innovation ecosystem, a secure data and connectivity infrastructure, and policies to ensure that the workforce is prepared for the impact of AI. This refresh builds on the solid foundations in place, continuing to emphasise the importance of trustworthy, person-centred AI development and use, while positioning Ireland as a leader in seizing AI's economic and societal benefits. It aims to balance innovation with proportionate regulation and trust-building measures. More info: AI Strategies and Policies in Ireland - OECD.AI	
General Data Protection Regulation (GDPR) General Data Protection Regulation (GDPR) **and** Data Protection Acts 1988 and 2003	2018	The General Data Protection Regulation (GDPR) applies from 25 May 2018. It has general application to the processing of personal data in the EU, setting out more extensive obligations on data controllers and processors, and providing strengthened protections for data subjects. Although the GDPR is directly applicable as a law in all Member States, it allows for certain issues to be given further effect in national law. In Ireland, the national law, which, amongst other things, gives further effect to the GDPR, is the Data Protection Act 2018. However, in some instances, depending on the nature and circumstances of the personal data processing, the type of personal data being processed, or when the data protection issue occurred, the GDPR will not apply and instead another legal framework concerning the regulation of the processing of personal data may apply. For example, if a data protection complaint or a possible infringement of the law relates to an incident which occurred before the GDPR became applicable on 25 May 2018, then the Data Protection Acts 1988 – 2003, and not the GDPR, will apply. After 25 May 2018, if the processing of personal data is carried out for a law enforcement purpose (in other words the prevention, investigation, detection or prosecution of a criminal offence or the execution of criminal penalties) then the GDPR will not apply and instead the Law Enforcement Directive, which has been transposed into Irish law by way of the Data Protection Act 2018, will apply.	Yes
Data Protection Act 2018: Data Protection Act 2018	2018	the "Law Enforcement Directive" (Directive (EU) 2016/680) which has been transposed into Irish law by way of the Data Protection Act 2018	Yes
ePrivacy the 2011 "ePrivacy Regulations" (S.I. No. 336 of 2011 – the European Communities	2011	From 25 May 2018, processing of personal data in the context of certain electronic communications (including, amongst other things, unsolicited electronic communications made by phone, e-mail, and SMS) is subject to both the general laws set out in the	Yes

(Electronic Communications Networks and Services) (Privacy And Electronic Communications) Regulations 2011)		GDPR and the specific laws set out in the "ePrivacy Regulations" (S.I. No. 336 of 2011, under which the ePrivacy Directive 2002/58/EC (as amended by Directive 2006/24/EC and 2009/136/EC) was transposed into Irish law).	
Medical Practitioners Act: https://www.irishstatutebook.ie/eli/2007/act/25/enacted/en/html	2007	An Act for the Purpose of Better Protecting and Informing the Public in Its Dealings with Medical Practitioners	Yes
Sláintecare Implementation: https://www.gov.ie/en/campaigns/slaintecare-implementation-strategy/	2018	Sláintecare reform is transforming how we deliver healthcare in Ireland, building towards equal access to services for every citizen based on patient need and not their ability to pay. By putting people at the centre of the health system and developing primary and community health services, the Department of Health and HSE are working together to provide new models of care that allow people to stay healthy in their homes and communities for as long as possible. The aim is to deliver the Sláintecare vision of one universal health service for all, providing the right care, in the right place, at the right time.	No
Digital Health Framework for Ireland: https://www.gov.ie/en/publication/0d21e-digital-for-care-a-digital-health-framework-for-ireland-2024-2030/	2024	This framework sets out a roadmap to digitally transform health services in Ireland and improve access for patients.	No
Digital Health Roadmap: https://assets.publications.hse.ie/media/file_based_publications/Digital_Health_Strategic_Implementation_Roadmap.pdf	2024	The primary purpose of the Roadmap is to set out digital health Initiatives which will deliver the vision and mission set out in the DOH's Framework. These Initiatives are prioritised and will be undertaken from year 1 to year 7 and the Roadmap highlights the benefits for patients, the population, the health workforce, and the overall health system in Ireland. The Roadmap aims to integrate and connect health and social care services, providing timely, efficient, and patient-centred care with ready access to high-quality up-to-date health information. The Roadmap recognises the need for significant and sustained investment to achieve transformational goals, including the implementation of Electronic Health Records (EHRs), and Shared Care Record (SCR), allowing a single point of access to health information for patients and staff	No
The Equal Status Acts 2000-2018: https://www.ihrec.ie/guides-and-tools/human-rights-and-equality-in-	2000 (currently	The Equal Status Acts 2000–2018 in Ireland prohibit discrimination in the provision of goods and services, accommodation and education. They cover the nine grounds of Age, Civil Status (formerly referred to as Marital Status), Disability, Family Status,	Yes

the-provision-of-good-and-services/what-does-the-law-say/equal-status-acts/	under review)	Gender, Membership of the Traveller Community, Race, Religion, Sexual Orientation. In addition, the Acts prohibit discrimination in the provision of accommodation services against people who are in receipt of rent supplement, housing assistance, or social welfare payments. Note: no specific protection for gender identity/expression or sex characteristics, or socio-economic status.	
The Employment Equality Acts 1998-2015: https://www.ihrec.ie/guides-and-tools/human-rights-and-equality-for-employers/what-does-the-law-say/eea-summary/	1998 (currently under review)	The Employment Equality Acts 1998-2015 prohibit discrimination under the nine grounds (Age, Civil Status, Disability, Family Status, Gender, Membership of the Traveller Community, Race, Religion, Sexual Orientation) in employment, including vocational training and work experience. The main obligations of employers under the act include the following: Employers may not discriminate against employees or potential employees on the basis of any of the nine grounds. Note: no specific protection for gender identity/expression or sex characteristics, or socio-economic status.	Yes
Review of Equality Acts: https://www.gov.ie/en/publication/d0187-the-review-of-the-equality-acts/	TBC	More information on the recent review of the Equality Acts, including the consultation and the approval of the General Scheme and Head of Bill in November 2024, arising from this review: https://www.gov.ie/en/publication/d0187-the-review-of-the-equality-acts/	

2.1.4.2. Spain

Table 7.Relevant national policies in Spain.

What	Applicable since	Description	Binding
Data protection Law: Ley Orgánica 3/2018 Reference: BOE-A-2018-16673	2018	It is Spain's national legislation that complements and adapts the EU General Data Protection Regulation (GDPR) to the Spanish legal framework. Enacted on 5 December 2018, it regulates the processing of personal data, strengthens the protection of fundamental rights and freedoms, and introduces specific provisions on digital rights in the workplace and educational environments.	Yes
Law 14/1986, de 25 de abril, General de Sanidad	1986	This General Health Law establishes that health is an indispensable condition for human development and a fundamental means for achieving individual and collective well-being.	Yes
Ley 16/2011, de 23 de diciembre, de Salud Pública de Andalucía	2011	It establishes the foundation for health promotion and the participation of local communities, including municipalities as key players, such as Local Health Action Network (RELAS).	Yes

Youth Strategy 2030 Estrategia de Juventud 2030 (EJ2030)	2002	The Youth Strategy 2030 (EJ2030) points out the psychological consequences of COVID-19 on children and youth and proposes among its objectives: Promote the mental well-being of youth, prevent suicide and end the stigmatization of mental health problems which consists of the following subsections: • Adapt and integrate health services for a system of prevention and early care in the field of mental health. • To care for young people with mental health problems, foster their emotional and personal development, and fight against the stigma of mental health and suicide. • Promote and collaborate with the associationism of young people and adolescents affected by mental health problems and suicidal behavior. • Promote systematic research for knowledge, prevention and good practices in the field of mental health, suicide and emotional well-being of adolescents and young people. • Tailor public services to the specific needs of adolescents and youth to improve their quality of life. EJ2030 will be implemented through three Action Plans, 2022-2024, 2025-2027 and 2028-2030.	No
Ley 1/2014, de 24 de Junio, de Transparencia pública de Andalucía	2014	This law provides some guidelines on the limits to the right of access to public information provided for in the basic regulations, especially those arising from the protection of personal data. Specifically, Chapter Two creates the Andalusian Transparency and Data Protection Council as an entity endowed with autonomy and independence to act as an independent supervisory authority in both the areas of transparency and data protection.	Yes
Ley 4/2021, de 27 de Julio, de Infancia y Adolescencia en Andalucía	2021	This law will apply to ALL minors within the territory of Andalusia. The purposes of this law include creating an information system on child and adolescent protection, complementary to the state information system, and regulating the exercise of the rights and obligations of this population (for example, the right to healthcare).	Yes
Decreto 246/2005, de 8 de noviembre, por el que se regula el derecho de las personas menores de edad a recibir atención sanitaria en condiciones adaptadas a las necesidades propias de su edad y desarrollo y se crea el consejo de salud de las personas menores de edad	2005	The purpose of this Decree is to regulate the exercise of the right of minors to receive healthcare in the Autonomous Community of Andalusia, establishing the conditions under which this care must be provided, with the aim of offering comprehensive, personalized healthcare tailored to their specific needs. It focuses more on areas such as human dignity, confidentiality, freedom, and violence (including female genital mutilation).	Yes
Ley 4/2023, de 28 de febrero, para la igualdad real y efectiva de las personas	2023	This law defines the public policies that will guarantee the rights of LGBTQIA+ people and removes the obstacles that prevent them from fully exercising their citizenship. It addresses a long-standing demand of LGBTQIA+ associations, which for decades have led and promoted	Yes

trans y para la garantía de los derechos de las personas LGTBI		the vindication of the rights of these groups. For example, Chapter I establishes the criteria and general guidelines for their action and establishes the duty to adapt public services to recognize and guarantee equal treatment of LGBTQIA+ people, the recognition and institutional support of diversity in matters of sexual orientation and identity, gender expression and sexual characteristics, and family diversity, and the dissemination and awareness-raising to foster respect for diversity.	
Regulation (EU) 2024/1689	February 2025 (Chapters I and II) and August 2026 the rest.	The main legislative instrument that will regulate the use of AI in Spain is Regulation (EU) 2024/1689 of the European Parliament and of the Council, approved on May 21, 2024, and published in the Official Journal of the European Union on July 12, 2024. Spain has established the Spanish Agency for the Supervision of Artificial Intelligence, which will be the main supervisory authority at the national level. The creation of this agency responds to the provisions of the European Regulation, which grants Member States the power to create one or more entities responsible for supervision. The Observatory on the Social and Ethical Impact of Algorithms (OBISAL) is another important initiative to monitor the effects of AI on society. Chapters I and II of the regulation, which address general provisions and prohibited practices, are applicable from February 2025. The rest of the Regulation will be applicable from August 2, 2026.	Yes
Ley Orgánica de Protección de Datos y Garantía de Derechos Digitales (LOPDGDD)	2018	The aim is to achieve the adaptation of the Spanish legal system to Regulation (EU) 2016/679 of the European Parliament and the Council, of April 27, 2016, General Data Protection Regulation, and to complete its provisions.	Yes
Ley 1/2024, por la que se crea el Instituto Andaluz de Salud Mental	2024	At the national level, there is no specific state law comprehensively regulating mental health, although there are sectoral and regional regulations. This law aims, among other objectives, to coordinate and functionally integrate all mental health-related resources legally owned by the various Public Administrations in Andalusia.	Yes
Ley Orgánica 1/2004, de 28 de diciembre, de Medidas de Protección Integral contra la Violencia de Género	2004	This law was a legislative milestone in comprehensively addressing violence against women, establishing preventive, educational, social, welfare, and victim care measures. One of the most significant aspects of this law was the creation of specialized judicial bodies: the courts for violence against women.	Yes
Ley 1/2021, de 24 de marzo, de medidas urgentes en materia de protección y asistencia a las víctimas de violencia de género	2021	It strengthens existing protection mechanisms and establishes additional measures to ensure assistance to victims, especially in emergency situations such as the one experienced during the COVID-19 pandemic.	Yes
La Ley Orgánica 8/2021, de 4 de junio, de protección integral a la infancia y la adolescencia frente a la violencia	2021	This legislation recognizes the negative impact that gender-based violence has on the cognitive and emotional development of children.	Yes
Ley Orgánica 10/2022 de Garantía Integral de la Libertad Sexual	2022	It represents an expansion of the protection framework by specifically addressing sexual violence as a form of gender-based violence. This law complements Organic Law 1/2004,	Yes

		extending protection to victims of sexual violence outside of the context of a sentimental partner or ex-partner.
ESTRATEGIA NACIONAL DE PREVENCIÓN Y LUCHA CONTRA LA POBREZA Y LA EXCLUSIÓN SOCIAL 2019-2023	2019	Led by the Ministry of Social Rights, this strategy: Targets people in poverty or social exclusion Integrates mental health as a social determinant Calls for coordinated action between health, employment, housing, and education services Includes groups such as: Long-term unemployed Roma communities Migrants and refugees Women in vulnerable situations	No
Plan Local de Intervención en Zonas Desfavorecidas de Sevilla	2018-2022	Focused on six disadvantaged areas of Seville. Promotes personalized pathways for social and labour inclusion. Develops 144 initiatives in areas such as education, family, security, housing, health, and employment.	No
LEY GENERAL DE DERECHOS DE LAS PERSONAS CON DISCAPACIDAD Y DE SU INCLUSIÓN SOCIAL	2013	This law, officially Royal Legislative Decree 1/2013, aims to guarantee the rights, equal opportunities, non-discrimination, and full social inclusion of people with disabilities in Spain. It consolidates previous laws and aligns with the UN Convention on the Rights of Persons with Disabilities. Key principles include: Non-discrimination, Universal accessibility, Gender equality, Full and effective participation in society It recognizes all types of disabilities, including mental illness, and pays special attention to those at risk of multiple discrimination.	Yes
Ley 4/2017, de 25 de septiembre, de los derechos y la atención a las personas con discapacidad en Andalucía	207	Law 4/2017 on the Rights and Care of Persons with Disabilities in Andalusia enhances regional protection. It promotes: Equal treatment and social participation, Accessibility in all areas of life (education, health, employment), Development of an Integral Action Plan for People with Disabilities.	Yes
Estrategia de Salud Mental del Sistema Nacional de Salud	2022-2026	The latest version was updated in 2022 for the period 2022–2026. It aims to improve prevention, care, and recovery for people with mental health conditions. Core objectives: • Promote mental well-being and prevent disorders • Guarantee early detection and treatment • Provide community-based care rather than institutionalization • Address suicide prevention • Include people with lived experience in the design of services • Emphasizes human rights, equity, and person-centered care.	No
Plan Andaluz de Infraestructuras para Salud Mental	2021-2024	It includes 21 projects to strengthen mental health infrastructure. It pays special attention to vulnerable groups and children and adolescents.	No
Plan Estratégico de Salud Mental de Andalucía (PESMAA)	2023	It establishes a comprehensive and equitable approach to mental health care. It emphasizes the humanization and digitalization of services.	No

		* The 2025-2027 National Mental Health Action Plan is pending approval due to a lack of support from the Interterritorial Council of the National Health System.	
III Plan de Infancia y Adolescencia de Andalucía 2024-2027	Approved in October 2024	It focuses especially on children and adolescents in situations of vulnerability, risk, or helplessness.	No
II Plan Integral para la Inclusión de la Comunidad Gitana de Andalucía	2023	It seeks to promote effective equality and the participation of the Roma population. It focuses on areas such as education, employment, housing, and health. It aims to promote gender equality and prevent gender-based violence among the Roma population. Its objective is to reduce health inequalities and improve access to housing and social services. It seeks to prevent anti-Roma behaviour and combat hate crimes, and promotes social participation and the appreciation of Roma culture.	No
Plan Local para la Cohesión e Inclusión Social. Ciudad de Sevilla (ERASCIS+)	2024-2028	It is funded with the Law of Social Services in Andalusia. The Local Plan for Cohesion and Social Inclusion (ERACIS+) in Seville is a strategy funded by the Regional Government of Andalusia and the EU (European Social Fund) that seeks to reduce social exclusion in disadvantaged areas through comprehensive interventions. Its main functions are: social and labor integration, access to basic services, community development, and inter-institutional coordination (coordinating actions with local stakeholders such as schools, NGOs, and government agencies to address inequalities across the board). In Seville, it is implemented in areas such as the Polígono Sur (South Industrial Estate), prioritizing the inclusion of vulnerable groups through multidisciplinary teams (social workers, educators, psychologists).	No
Estrategia Nacional para la Igualdad, Inclusión y Participación del Pueblo Gitano 2021-2030		The Spanish government has developed the "National Strategy for Equality, Inclusion, and Participation of the Roma Community 2021-2030" to enhance the social inclusion and participation of the Roma population. This strategy aligns with the European Framework and incorporates lessons learned from previous initiatives. It focuses on three main areas: 1. **Social Inclusion**: Improving education, employment, housing, essential services, health, poverty reduction, social exclusion, and bridging the digital gap. 2. Equality and Non-Discrimination: Combating antigypsyism, promoting gender equality, preventing violence against women, and recognizing Roma culture. 3. Participation and Empowerment: Encouraging active participation of the Roma community and strengthening Roma associations. The strategy prioritizes women, children, and mobile citizens and migrants. It is implemented through two operational plans covering 2021-2026 and 2027-2030, with evaluations planned for 2026 and 2030.	No
Real Decreto 891/2005, de 22 de julio, por el que se crea y regula el Consejo Estatal del Pueblo Gitano (CEPG)	2005	The Real Decreto 891/2005, dated July 22, 2005, establishes and regulates the Consejo Estatal del Pueblo Gitano (CEPG) in Spain. This consultative and advisory body aims to formalize the participation and collaboration of organizations related to the Roma community in the development of public policies, particularly those concerning social welfare and the promotion of equality. Key objectives of the CEPG include:	Yes

		• Promoting Participation: Encouraging the involvement of Roma associations in shaping policies that affect their community. • Advising the Government: Providing recommendations on the design, implementation, and evaluation of programs aimed at the comprehensive development of the Roma population. • Ensuring Equality: Working towards equal opportunities, treatment, and non-discrimination for Roma individuals • Fostering Social Cohesion: Promoting harmonious coexistence among diverse cultural groups within Spanish society.	
Ley 9/2016, de 27 de diciembre, de Servicios Sociales de Andalucía	2016	This regional law governs the public social services system in Andalusia, with the aim of guaranteeing universal access to social benefits and services under equal conditions. Its main characteristics are: • It promotes the universal right to social benefits and services, seeking individual and social development. • It guarantees access to resources for decent living conditions, social integration, and personal autonomy. • It establishes the right as universal, although some benefits are subject to the availability of resources.	Yes
Ley Orgánica 4/2000, de 11 de enero, sobre derechos y libertades de los extranjeros en España y su integración social	2000	It regulates the rights and freedoms of foreigners in Spain, their entry, stay, and exit, family reunification, and social integration. It recognizes fundamental rights, sets rules for residency and work, and establishes penalties for violations such as illegal stay. It also promotes integration through access to education and employment. It has been amended several times to tighten immigration control and adapt the regulations to social and European changes.	Yes
Estrategia Andaluza para la Inmigración 2021-2025: Inclusión y Convivencia	2021	The Strategy aims to be the general planning instrument of the Autonomous Community of Andalusia for policies that promote the social integration of migrants and applicants and beneficiaries of international protection, seeking to develop and encourage interaction between the key policies that promote their social integration and the promotion and strengthening of an integrating society and intercultural coexistence.	No
Estatuto de Autonomía para Andalucía	2007	Article 10.3.17 as a basic objective of the Autonomous Community the social, economic, labor and cultural integration of immigrants in Andalusia. In similar terms it is included in Article 37.1.9 as a guiding principle of public policies. Likewise, Article 62 of the Statute refers exclusively to immigration, stating, among other matters, that the Autonomous Community is responsible for the policies of integration and social, economic and cultural participation of immigrants, within the framework of its competences.	Yes

2.1.4.3. France

1. Mental health

Table 8.Relevant national policies in France.

What	Applicable since	Description	Binding
Public Health Code: Book II – Combating Mental Illness	1953 (updated on a regular basis)	This book defines France's mental health policy, covering prevention, diagnosis, care, rehabilitation, and social reintegration. It also outlines the organization of psychiatry, notably through the development of territorial mental health projects to ensure appropriate care nationwide.	**Yes**
Law of March 4, 2002, on Patients' Rights and the Quality of the Healthcare System	2002	Known as the "Kouchner Law," this law establishes patients' rights, including those in psychiatry. It guarantees direct access to medical records, strengthens patient representation in healthcare institutions, and provides compensation for medical accidents, even in the absence of fault.	**Yes**
Law of July 5, 2011, modified by the Law of September 27, 2013, on Psychiatric Care without Consent	2011 - 2013	These laws regulate psychiatric care without patient consent, defining admission procedures and safeguarding patients' rights and freedoms. They distinguish two main admission procedures: one by the hospital director's decision and another by the representative of the State.	**Yes**
Law of February 11, 2005, for Equal Rights and Opportunities, Participation, and Citizenship of Persons with Disabilities	2005	This law introduces a legal definition of disability, including mental disorders, and aims to ensure equal rights and opportunities for people with disabilities, particularly in employment, education, and healthcare.	**Yes**
Law of June 27, 1990, on the Rights and Protection of People Hospitalized for Mental Disorders	1993	This law introduced provisions concerning voluntary and involuntary psychiatric hospitalization, establishing procedures to protect patients' rights while ensuring appropriate care.	**Yes**
Criminal Code: Article 122-1	2014	This article states that individuals suffering from mental disorders that abolished their judgment at the time of the act are not criminally responsible. Instead, they may be subject to appropriate security measures.	**Yes**
Law of August 9, 2004, on Public Health Policy	2004	This law strengthened France's mental health policy by defining specific objectives, particularly regarding the prevention and management of mental disorders and the improvement of psychiatric care quality.	**Yes**
Law of January 26, 2016, on the Modernization of the Healthcare System	2016	This law introduced measures to improve psychiatric patient care, particularly by promoting mental health prevention and strengthening patient rights.	**Yes**
Bill No. 465 to Address the Urgency in Psychiatry and Mental Health	2022	Filed on November 15, 2022, this bill seeks to address current challenges in psychiatry and mental health by proposing measures to improve access to care and increase resources allocated to the sector.	No
Decree No. 2017-1200 of July 27, 2017, on the Territorial Mental Health Project (PTSM).	2017	This decree defines the framework for PTSMs, aiming to enhance the coordination of local stakeholders and improve access to care for individuals with mental disorders. It identifies six key priorities that each PTSM must integrate: 1) Prevention and early detection of mental disorders, 2) Improving access to appropriate care and support, 3) Ensuring continuity of	**Yes**

		care and support pathways, 4) Promoting psychosocial rehabilitation and social inclusion, 5) Developing research and innovation in mental health, 6) Training and supporting informal caregivers and professionals. These priorities are designed to structure a coherent and tailored healthcare offer, addressing the specific needs of each region while involving all relevant stakeholders, including users and their families. Additionally, the 2017 decree emphasizes psychosocial rehabilitation, an approach aimed at fostering autonomy and social inclusion for individuals with mental disorders. This discipline, integrated into public policies through this decree, promotes early and personalized interventions to improve patients' quality of life.	
National strategy for Psychiatry and Mental Health 2018-2026	2018	This program continues the work of the 2013-2017 "Psychiatry and Mental Health" (HAS) initiative and was developed to address the needs and concerns of various stakeholders, including users, professionals, and institutions. It also ensures complementarity and consistency in the work carried out within the HAS. As a multi-year and evolving framework, the program's main guidelines and planned initiatives may be adjusted over time. These modifications will take into account new institutional referrals, discussions with the members of the HAS "Psychiatry and Mental Health" monitoring committee, and the results of scoping and feasibility studies conducted for different planned projects.	No
Order n°2018-20 of January 17, 2018, art 11	2018	Military hospitals and the Armed Forces Health Service contribute to France’s mental health policy by participating in territorial mental health assessments and projects, subject to Defense Ministry approval. Any territorial mental health contract involving military units requires ministerial authorization and is annexed to broader defense agreements. Once approved, military hospitals can join regional psychiatric communities. In regions with specific defense needs, the Armed Forces Health Service helps develop the shared territorial mental health project.	**Yes**
Order n°2021-583 of May 12, 2021, art1	2021	The sector-based psychiatry mission ensures proximity psychiatric care, including ambulatory and home interventions, in collaboration with primary care teams and health professional communities. It guarantees accessibility to care and continuity, particularly for complex cases, including hospitalization (with or without consent) and necessary referrals. This mission is part of the care gradation system and includes provisions for children and adolescents. Health institutions also contribute to prevention, care, and reintegration through the territorial mental health project.	**Yes**

2. People in vulnerable situations

What	Applicable since	Description	Binding

Code of Entry and Residence of Foreigners and the Right of Asylum (CESEDA)	2009 (updated on a regular basis)	Right to Asylum: Enshrined in the French Constitution and detailed in the Code of Entry and Residence of Foreigners and the Right of Asylum (CESEDA), France recognizes the right of individuals persecuted for their actions in favor of liberty to seek asylum within its territory. Applicability of the Geneva convention, International and European law.	Yes
Anti-Discrimination Laws, Law No. 2001-1066 of November 16, 2001	2001	France has enacted various laws to protect individuals from discrimination based on sexual orientation and gender identity. These protections have been integrated into the legal system over time, with significant advancements made in the early 2000s. Notably, the inclusion of sexual orientation as a protected characteristic in anti-discrimination legislation occurred with the enactment of Law No. 2001-1066 of November 16, 2001, which entered into force shortly after its promulgation.	Yes
Law No. 2005-102 of February 11, 2005, "For Equal Rights and Opportunities, Participation, and Citizenship of Persons with Disabilities"	2005	This comprehensive legislation aims to ensure equal rights and opportunities for individuals with disabilities, emphasizing accessibility, integration, and support across various sectors, including employment and education. The law entered into force on February 11, 2005.	Yes
Law No. 2004-626 of June 30, 2004,	2004	French social security and healthcare systems provide various benefits and support services tailored to the needs of the elderly, aiming to ensure their well-being and integration within society. These provisions have been established through multiple legislative acts over the years, with key frameworks such as the establishment of the National Solidarity Fund for Autonomy (CNSA) created by Law No. 2004-626 of June 30, 2004, which entered into force on that date.	Yes
Law No. 2008-1249 of December 1, 2008	2008	The RSA, (roughly translated : Active solidarity income) designed to support individuals and families with low income, was established by Law No. 2008-1249 of December 1, 2008. The law entered into force on June 1, 2009, providing financial assistance to reduce poverty and promote social inclusion. (without children for one person : 565e/month)	Yes
Enacted as Law No. 2007-290 of March 5, 2007, and entering into force on January 1, 2008	2008	This law guarantees the enforceable right to housing, allowing individuals without adequate housing to seek legal recourse to obtain accommodation.	yes
LAW No. 2007-308 of March 5, 2007 reforming the legal protection of adults	2007	This law introduces measures of legal protection adapted to people whose health is affected by age, disability or illness.	yes
LAW No. 2024-317 of April 8, 2024, providing measures to build a	2024	This law aims to strengthen the management of the policy to prevent the loss of autonomy and combat social isolation, with the goal of reducing vulnerability and enhancing the well-being of individuals facing these challenges. The law also aims at promoting good treatment by addressing the abuse of people in vulnerable situations and ensuring the protection of their fundamental rights.	yes

society of healthy aging and autonomy		strengthening the autonomy of vulnerable adults by applying the principle of subsidiarity, supporting them in maintaining their independence with community-based solutions is also a major objective. Finally, it aims at guaranteeing quality housing conditions and accessible services for vulnerable individuals, ensuring they have access to professional support practices that enhance their overall quality of life.	

3. Data

What	Applicable since	Description	Binding
January 6, 1978 (initially), with major updates to align with GDPR.	1978 (updated on a regular basis)	The **Loi Informatique et Libertés** was the original French law governing the protection of personal data. It has been updated several times, notably in 2004 and 2018, to comply with the GDPR. This law defines the framework for processing personal data and outlines rights such as access, correction, and deletion of personal information.	Yes
Decree No. 2005-1309 on the Implementation of the Data Protection Act	October 20, 2005	This decree provides detailed rules for the implementation of the French Data Protection Act. It governs the registration process for personal data files and ensures that data controllers comply with security measures to protect personal data.	Yes
Decree No. 2018-687 on the CNIL's Powers and Procedures	2018	This decree outlines the powers and procedures of the Commission Nationale de l'Informatique et des Libertés (CNIL), which is the French data protection authority. It includes rules for how the CNIL handles complaints, investigations, and enforcement actions related to the GDPR.	Yes
Law No. 2016-1321 on Digital Republic	October 7, 2016	This law provides a modern framework for data protection, particularly in the digital environment. It strengthens privacy protections, introduces a right to digital portability, and reinforces transparency in how personal data is collected by digital platforms.	Yes

4.AI

What	Applicable since	Description	Binding
Law No. 2016-1321 for a Digital Republic (Loi pour une République numérique)	2016	This law aims to improve transparency in the digital world, including AI. It promotes innovation, data accessibility, and privacy protection. It also defines frameworks for the use of AI in various sectors, with an emphasis on citizen rights and digital ethics.	Yes
Decree No. 2019-1088 on the National Commission for Digital Technology (CNNum)	October 17, 2019	The decree established the Commission Nationale du Numérique (CNNum) to advise on issues related to digital innovation, including the use of AI. It provides guidance on ethical concerns surrounding AI applications, such as transparency, fairness, and accountability in AI systems.	Yes

Law No. 2019-761 on the Implementation of the GDPR (General Data Protection Regulation)	2019	This law enacts provisions of the GDPR into French national law, particularly focusing on the processing of personal data, which directly impacts AI technologies that collect, process, or store personal information. AI systems must comply with data protection regulations under the GDPR, which apply to all sectors using AI.	Yes
France 2030 : National Strategy for International Intelligence	2018	In 2018, the French government launched a national AI strategy composed of 2 phases. Phase 1 (2018-2022): providing France with competitive research capabilities Phase 2 (2021-2025): disseminating artificial intelligence technologies within the economy This strategy aims to position France as one of the European and global leaders in artificial intelligence (AI).	No

2.1.4.4. Germany

Table 9.Relevant national policies in Germany.

What	Applicable since	Description	Binding
Recommendations for the assessment of clinical studies by ethics committees ISBN 978-3-7691-1305-1 https://www.gesundheitsforschung-bmbf.de/files/Empfehlungen_zur_Begutachtung_2012.pdf	2012	Guidelines for ethics committees: “Recommendations for the assessment of clinical studies by ethics committees” (published by the BMBF) is a comprehensive work that standardizes the assessment of studies.	No
EU Clinical Trials Regulation (EU Regulation 536/2014)	2014 (fully applicable in Germany since January 2022)	Harmonizes rules for conducting clinical trials in the EU. Ensures participant safety, data transparency, and simplifies cross-border trial authorization via the Clinical Trials Information System (CTIS). Directly applicable in Germany and overseen by BfArM and ethics committees.	**Yes**
Human and Machine – Challenges posed by Artificial Intelligence https://www.ethikrat.org/fileadmin/Publikationen/Stellungnahmen/deutsch/stellungnahme-mensch-und-maschine.pdf Regulierung von künstlicher Intelligenz in Deutschland unter besonderer	2023	The German Ethics Council's statement "Mensch und Maschine – Herausforderungen durch Künstliche Intelligenz" examines the ethical implications of artificial intelligence (AI) across four key areas: 1. **Medicine**: AI offers advancements in diagnostics and personalized treatments but raises concerns about patient autonomy and data privacy. 2. **Education**: Integrating AI in schools can personalize learning but may impact teacher roles and student development.	no

Berücksichtigung des Gesundheitswesens

3. **Public Administration**: AI can enhance efficiency but necessitates transparency to maintain public trust.
4. **Public Communication and Opinion Formation**: AI's role in content creation and dissemination can influence public opinion, highlighting the need for media literacy and regulation.

The Council emphasizes that AI should augment, not diminish, human agency and responsibility. They advocate for regulations ensuring AI aligns with human rights and democratic values, promoting transparency, accountability, and inclusivity in AI development and deployment.

Social Code Book V (SGB V) – Statutory Health Insurance	1989	Framework for statutory health insurance, including coverage for mental health services, rehabilitation, and psychotherapy. Governs coordination and access to mental health care.	**Yes**
Federal Child Protection Act (Bundeskinderschutzgesetz, BKiSchG)	2012	Establishes procedures for reporting child welfare risks and promotes early intervention and collaboration, including in cases related to child and adolescent mental health.	**Yes**
National Mental Health Strategy (Nationale Strategie für psychische Gesundheit)	2020	A federal strategy to strengthen prevention, destigmatization, community-based care, and coordination across sectors for mental health across the life span.	No
Federal Participation Act (Bundesteilhabegesetz, BTHG)	2017 (phased)	Enhances inclusion and self-determination of persons with disabilities, including mental health-related disabilities. Ensures access to services and participation in society.	**Yes**
General Equal Treatment Act (Allgemeines Gleichbehandlungsgesetz, AGG)	2006	Prohibits discrimination based on ethnicity, gender, religion, disability, age, and sexual orientation in employment, education, and services.	**Yes**
National Action Plan on Integration (NAP-I)	2012, updated 2021	Policy framework for integrating migrants and refugees, focusing on education, employment, healthcare, and anti-discrimination.	No
National Action Plan Against Racism – Measures for Roma Inclusion	2017 (updated 2022)	Includes anti-discrimination measures and promotion of participation, education, and integration of Roma in line with EU Roma Framework.	No
German Ageing Strategy (Altersstrategie der Bundesregierung)	2020	Aims to improve the quality of life, participation, digital inclusion, and health care access for older people. Linked to the WHO Decade of Healthy Ageing.	No
Youth Strategy 2015–2025 (Jugendstrategie der Bundesregierung	2015	A cross-sectoral federal strategy to support youth participation, well-being, education, and inclusion, especially in vulnerable contexts.	No

Federal Data Protection Act (Bundesdatenschutzgesetz, BDSG)	2018 (revised)	Implements the GDPR in Germany. Sets national rules for the protection of personal data, individual rights, and supervisory authority responsibilities.	**Yes**
Digital Healthcare Act (Digitale-Versorgung-Gesetz, DVG)	2019	Enables use and reimbursement of digital health applications (DiGAs), supports e-health infrastructure and strengthens patient data protection.	**Yes**
Online Access Act (Onlinezugangsgesetz, OZG)	2017	Mandates digital access to public administration services, including secure data handling and interoperability across government platforms.	**Yes**
German AI Strategy (Strategie Künstliche Intelligenz der Bundesregierung)	2018 (updated 2020)	Defines objectives and funding for AI research, ethical standards, societal inclusion, and transparent development of AI technologies.	No
Federal Government's Ethics Guidelines for Automated and Connected Driving	2017	Outlines ethical requirements and accountability in the use of AI in mobility, including transparency, user autonomy, and protection of human dignity.	No
EU AI Act (Regulation (EU) 2024/1689)	2025 (phased)	As an EU Regulation, it will be directly applicable in Germany. Regulates high-risk AI systems, requires transparency, human oversight, and rights protection.	**Yes**

2.1.4.5. Türkiye

Table 10.Relevant national policies in Türkiye.

What	Applicable since	Description	Binding
National Menal Health Action Plan (2023-2030) https://hsgm.saglik.gov.tr/depo/Yayinlarimiz/Eylem_Planlari/Ulusal_Ruh_Sagligi_Eylem_Plani_2021-2023.pdf	**2023**	Türkiye's mental health policy is primarily guided by the National Mental Health Action Plan (2023–2030), which aligns with WHO guidelines. The plan emphasizes community-based mental health services, integration into primary care, and reducing stigma. Mental Health Centers (Toplum Ruh Sağlığı Merkezleri - TRSM) are expanding across the country to provide outpatient psychosocial services, particularly for severe mental disorders. However, access and service quality can vary, especially in rural and underserved areas. **There is no legislation or law for mental health services yet, however it is in progress.**	No
Law No. 2828 on Social Services **Law No. 6284 preventing violence against women and protecting at-risk family members**		The Ministry of Family and Social Services in Türkiye operates under several key laws that ensure the protection and inclusion of vulnerable groups. Law No. 2828 on Social Services provides the foundation for delivering care and support to children, the elderly, persons with disabilities, and those at social risk. Law No. 6284 focuses on preventing violence against women and protecting at-risk family members through shelters and emergency measures. Law No. 5378 guarantees the rights of persons with disabilities, promoting accessibility, inclusion, and employment. For	**Yes**

Law No. 5378 **guarantees the rights of persons with disabilities** Law No. 5395 **on Child Protection** Temporary Protection Directive **for foreigners**		children, Law No. 5395 on Child Protection mandates preventive and rehabilitative services for those facing neglect or abuse. Additionally, in cooperation with the Directorate General of Migration Management, the Ministry supports vulnerable refugees and migrants, especially women and unaccompanied minors, through psychosocial and shelter services.	
Law on the Protection of Personal Data (KVKK)	2016	Türkiye's data protection framework is governed by the Law on the Protection of Personal Data (KVKK), enacted in 2016. It is largely modeled after the EU's GDPR but has some differences, particularly in cross-border data transfers and legal bases for processing. The Personal Data Protection Authority (KVKK Kurumu) oversees compliance. The law requires explicit consent for processing personal data, including sensitive data like health records. Recent debates involve balancing national security and individual privacy, especially in digital health and surveillance systems.	**Yes**
National Artificial Intelligence Strategy (2021–2025)		Türkiye adopted its first National Artificial Intelligence Strategy (2021–2025), aiming to increase AI's contribution to GDP and develop an ethical, secure AI ecosystem. It emphasizes human-centered AI, data governance, training the workforce, and international collaboration. The Digital Transformation Office coordinates AI policy, but **a comprehensive legal framework specific to AI ethics, risk assessment, and liability is still in progress.**	**No**

2.1.4.6. Greece

Table 11.Relevant national policies in Greece.

What	Applicable since	Description	Binding
National Action Plan for Mental Health (2021–2030) https://www.moh.gov.gr/articles/health/domes-kai-draseis-gia-thn-ygeia/c312-psyxikh-ygeia/c685-draseis/11499-ethniko-sxedio-drashs-gia-thn-psyxikh-ygeia	2023	The national action plan for mental health is structured around ten intervention axes. Its primary focus is the completion of deinstitutionalization, transitioning from traditional psychiatric hospitals to community-based services. This shift aims to enhance the quality of care and integrate individuals with mental health conditions into society more effectively. https://national-policies.eacea.ec.europa.eu/youthwiki/chapters/greece/75-mental-health	No

Completion of Psychiatric Reform http://elib.aade.gr/elib/view?d=/gr/act/2024/5129/	2024	In July 2024, the Greek parliament passed Law 5129/2024 to reform the structure and governance of mental health institutions. This legislation established the National Network of Mental Health Services, aiming to unify all mental health units within the National Health System, private psychiatric clinics, and NGOs into a cohesive network. Additionally, it created the National Organization for the Prevention and Treatment of Addictions to oversee addiction-related services nationwide.	Yes
Guidelines for most common health problems in primary healthcare by General Doctors (GPs)/family doctors (2017)	2017	The first guidelines for the management and treatment of the most common health problems including depression and general anxiety disorder by General/family doctors in primary healthcare. "Development of 13 General Medicine Guidelines for the management of the most common diseases and health conditions in Primary Health Care," Project Code: MIS 464637, under the Operational Programme "Administrative Reform 2007–2013".	No
National Strategy for Quality of Care and Patient Safety 2025–2030 https://www.who.int/europe/news-room/events/item/2025/01/30/default-calendar/greece-launches-its-new-national-strategy-for-quality-of-care-and-patient-safety-2025-2030?	2025	Launched in January 2025, this strategy focuses on improving healthcare quality and patient safety. It emphasizes leadership, governance, evidence-based practices, and patient engagement, all of which are essential for integrating digital health solutions effectively	No
National eHealth Interoperability Framework **https://reform-support.ec.europa.eu/what-we-do/health-and-long-term-care/design-and-implementation-national-ehealth-interoperability-framework-greece_en**	2019	In 2019, Greece, with support from the European Commission, designed the National eHealth Interoperability Framework. This initiative aimed to establish standardized communication protocols among various eHealth solutions, ensuring efficient data exchange and system interoperability across the healthcare sector.	No
Free access to health care services for vulnerable populations https://migrant-integration.ec.europa.eu/library-document/law-43682016-article-33-free-access-health-care-services_en	2016	The Greek Parliament has passed Law 4368/2016, which contains a new provision (Article 33) for the right of free access to the services of the Greek Public Health System by all refugees, asylum-seekers and beneficiaries of international protection, as well as those residing in Greece on humanitarian grounds or for exceptional health reasons.More broadly, the new law aims to ensure free access to health services by members of vulnerable groups in general, such as minors, pregnant women and individuals with disabilities.	Yes

General Secretariat for Vulnerable Persons & Institutional Protection https://migration.gov.gr/en/grammateies/geniki-grammateia-evaloton-politon-kai-thesmikis-prostasias/	2023	The General Secretariat for Vulnerable Persons and Institutional Protection was established with the Presidential Decision 77/2023 (Government Gazette A' 130/ 27-06-2023) to which the services of the Special Secretariat for the Protection of Unaccompanied Minors of article 39 of the P.D. 106/2020 were transferred and falls under the responsibilities of the Deputy Minister of Migration and Asylum. The General Secretariat for Vulnerable Persons and Institutional Protection, as the competent authority for all the issues regarding the unaccompanied minors in the country, has as its strategic objective the planning, implementation and supervision of the National Strategy for the protection of unaccompanied minors, as well as other policies and interventions to ensure the protection of unaccompanied and separated children, third-country nationals or stateless persons who are in Greece.
Greek Policy for Social Integration https://migration.gov.gr/en/migration-policy/integration/politiki-entaxis-se-ethniko-epipedo/	2019	Social integration is a process that entails mutual accommodation by third-country nationals (migrants, applicants, or beneficiaries of international protection) and Greek residents. Successful social integration leads to peaceful co-existence, respect for diversity and social cohesion. The current National Strategy for Social Integration was issued in July 2019, following revisions and developments of the National Social Integration Strategy of 2013. The National Strategy of 2019 contends-based on specifications from the European Council and the European Union, that a successful social integration policy requires the active participation of the State, Institutions, and civil society.
National Emergency Response Mechanism (NERM) https://migrant-integration.ec.europa.eu/index.php/integration-practice/greece-national-emergency-response-mechanism_fr	2022	Initially designed by the Special Secretariat for the Protection of Unaccompanied Minors (now the General Secretariat for Vulnerable Citizens and Institutional Protection) and the UNHCR in 2020, was implemented in Greece in 2021 and institutionalised in 2022. Its primary goal is to identify and provide immediate housing in emergency accommodation structures for unaccompanied minors (UAMs) living in homelessness or precarious conditions. This then facilitates connections between vulnerable individuals and relevant reception and care authorities, hospitals, and health and social care services
Mental health at work, using WHO guidance https://www.who.int/europe/news-room/10-10-2024-greece-takes-steps-to-improve-mental-health-at-work--using-who-guidance	2024	Recognizing the critical link between mental health and work, Greece has taken impressive steps to support employees in Athens. In a pioneering move, the nongovernmental organization Thalpos Mental Health, in collaboration with the Ministry of Health of Greece, established the first-ever national Workers' Day Center in 2023. The Center aims to prevent mental health conditions, promote mental well-being and support mental health at work, following WHO guidelines. The Workers' Day Center caters to employees seeking support to enhance their mental health and well-being, address mental conditions, manage psychosocial risks in the workplace, change organizational culture and access social welfare services.

Child and Adolescent Mental Health Initiative (CAMHI) http://elib.aade.gr/elib/printview?d=/gr/act/2023/5015	2021	Launched in early 2021, CAMHI is a five-year program aimed at strengthening mental health care capacity for children and adolescents in Greece. This initiative focuses on prevention, assessment, and treatment of mental health challenges faced by the youth. It represents a collaboration between the Stavros Niarchos Foundation (SNF) and the Greek state, under the auspices of the Ministry of Health. The initiative was formalized through Law No. 5015/2023	No
National Strategy to Combat Youth Internet Addiction https://better-internet-for-kids.europa.eu/en/sic/greece?utm_source=chatgpt.com	2024	In December 2024, Greece introduced a national strategy to protect minors from internet addiction and excessive social media use. The strategy includes strengthening parental controls, age verification, and collaboration with social media platforms. A dedicated website provides user-friendly guides, and a digital wallet application for parental control and age verification is set to launch in 2025.	No
The Hellenic Republic's Statements of Commitment to the Global Alliance Against Hunger and Poverty https://globalallianceagainsthungerandpoverty.org/wp-content/uploads/2024/11/Greece-SoC-Approved.pdf	2024	The Hellenic Republic hereby voluntarily joins the Global Alliance Against Hunger and Poverty and states its dedication to pursue the Alliance's mission, objectives and principles, as expressed in the Global Alliance's Terms of Reference and Governance Framework, and to collaborate with other members to achieve lasting solutions to poverty and hunger worldwide. The New Greek National Strategy for Social Inclusion and Poverty Reduction 2021-2027 is a comprehensive framework designed to tackle poverty and social exclusion by promoting equality and fostering resilience. It aligns with the European Pillar of Social Rights and the UN Sustainable Development Goals (SDGs). The Ministry of Foreign Affairs of Greece has initiated a programme for the establishment of Fetal Medicine Units and relevant training in cooperation with the FetaMedicine Foundation, London, in five countries (Ethiopia, Albania, Armenia, North Macedonia, Republic of Moldova) and Kosovo.	No

What	Applicable since	Description	Binding
Law 1316/1983 – Establishment, Organization, Jurisdiction, and Responsibilities of the National Organization for Medicines (EOF)	1983, with subsequent amendments	The foundational legal framework for the regulation of all medicinal products as well as other health products in Greece. It also established the National Organization for Medicines (EOF) — the Greek equivalent of the European Medicines Agency (EMA) or the U.S. FDA. It is relevant as it also applies to medicine concerning mental health.	**Yes**

National Legislation on Patients' Rights in Greece https://eu-healthcare.eopyy.gov.gr/en/patients-rights/national-legislation-on-patients-rights-in-greece/	2016	Establishes the rights of patients in Greece, including the right to dignity, informed consent, confidentiality, access to information, quality of care, and respect for cultural and personal values. Applies to all patients, including individuals with mental health conditions, and reinforces the protection of vulnerable populations within the healthcare system.	**Yes**
Law 2071/1992 – Modernization and Organization of the Health System	1992, with subsequent amendments	A legal framework that restructured Greece's healthcare system, introducing key reforms to improve service delivery, efficiency, and patient protection. A central part of the law is the formal recognition of patients' rights, including the right to informed consent, access to medical records, privacy, and dignified treatment—applicable across all medical fields, including psychiatric care. Article 47 of the law established the Charter of Patients' Rights, aligning national healthcare practices with European and international standards for ethical and patient-centered care.	**Yes**
Presidential Decree 340/1993 – Code of Pharmaceutical Ethics	1933	The official code of ethics for pharmacists in Greece, establishing their professional, legal, and moral obligations toward patients, society, and the state. It sets rules for the appropriate dispensation of medicines, including psychiatric medications, ensuring the protection of public health and the prevention of misuse. The decree also regulates pharmacists' relationships with healthcare professionals and emphasizes their duty to uphold scientific responsibility and continuous professional development.	
Ministerial Decision "ΔΥΓ3α/Γ.Π" 32221/2013 – Regulation of Prescription and Dispensation of Narcotic and Psychotropic Substances	2013	This decision provides detailed guidelines on the prescription and monitoring of medications containing controlled substances. It sets out the necessary documentation and procedures for healthcare providers when prescribing psychiatric drugs with potential for abuse.	
Law 3459/2006 – Code of Laws on Narcotic Drugs	2006, with subsequent amendments	This legislation outlines the control and distribution of narcotic substances, including certain psychiatric medications classified as controlled substances due to their potential for abuse or dependence. It specifies the conditions under which these medications can be prescribed and dispensed, emphasizing the necessity for medical justification and appropriate documentation.	**Yes**
Data Protection https://iclg.com/practice-areas/data-protection-laws-and-regulations/greece https://www.dpa.gr/en	2019	Greece adheres to the General Data Protection Regulation (GDPR), providing a unified legal framework for data protection across the European Union. In addition to the GDPR, Greece has enacted Law 4624/2019, which supplements the GDPR provisions and establishes the Hellenic Data Protection Authority (HDPA) as the supervisory authority responsible for monitoring compliance and imposing sanctions for data protection violations.	**Yes**

The Hellenic Data Protection Authority is a constitutionally established independent public authority, which has as its mission the supervision of the application of the General Data Protection Regulation (GDPR), national laws 4624/2019 and 3471/2006, as well as other regulations concerning the protection of the individual from the processing of personal data.

2.1.4.7. Bulgaria

Table 12.Relevant national policies in Bulgaria.

What	Applicable since	Description	Binding
Health Act: Chapter Five of this law (Art. 147 - Art. 162)	2005	Chapter Five of this law (Art. 147 - Art. 162) is dedicated to mental health, including: The rights of persons with mental disorders; Conditions and procedures for compulsory treatment and placement; Control over activities related to psychiatric care; The role of courts and medical institutions.	**Yes**
Criminal Code (CC)	1968	Regulates the criminal liability of persons with mental disorders; Conditions for placement in psychiatric institutions in the presence of public danger;	**Yes**
Code of Civil Procedure (CCP)	2007	Refers to the procedure of placement in a psychiatric institution without consent (compulsory treatment) by court decision;	**Yes**
Social Services Act (SSA)	2019	The main law regulating access to social services, including for people in vulnerable groups. Includes principles such as individual approach, equal access, participation and community support. Regulates the provision of residential, mobile and day services. It also regulates the provision of social support for people with mental illness, including community services and residential care.	**Yes**
Disability Act	2019	Provides a legal framework to support persons with physical, sensory, intellectual and mental disabilities. Regulates personal assistance, technical aids, individual needs assessment. Introduces employment quotas and integration support.	**Yes**
Law on protection against discrimination (*Закон за защита от дискриминация*)	2004	Prohibits discrimination on all grounds, including sex, age, ethnicity, disability, social status, etc. Protects the rights of vulnerable groups in all areas - education, employment, access to services. This comprehensive legal framework underscores Bulgaria's commitment to promoting equality and protecting the rights of all individuals, particularly those in vulnerable situations.	**Yes**
Child Protection Act (CPA)	2000	The Child Protection Act (CPA) of Bulgaria, enacted in 2000, is the cornerstone of the nation's child welfare framework. It establishes the legal basis for safeguarding children's rights and outlines the responsibilities of state and municipal bodies in child protection activities. It guarantees the rights of children at risk, including abandoned children, children in institutions, abused or disabled. Includes social protection measures, guardianship, foster care.	**Yes**

National Mental Health Strategy (2021-2030) (Националната стратегия за психично здраве на гражданите на Р България 2021- 2030)	2021	A non-binding document that sets a framework for improving mental health care, deinstitutionalisation, and service integration in the country.	No
National Youth Strategy 2021-2030 (Национална стратегия за младежта 2021-2030)	2021	The National Youth Strategy 2021–2030 (Национална стратегия за младежта 2021–2030) is a key strategic document adopted by the Bulgarian government, outlining the country's youth policy priorities for the decade. It aims to empower young people to realize their full potential and actively contribute to the development of Bulgaria within the European and global context.	No
Personal Data Protection Act (PDPA)	2019	Bulgarian law aligning national data protection with GDPR; establishes national data protection authority.	**Yes**
National Strategy for AI Development (2020–2030)	2020	Sets national priorities for AI development, ethics, education, and integration with EU frameworks.	No

4. Ethics and gender aspects of the AI-based Assistant

4.1 Purpose and function

The EQUICARES AI-based Assistant is a personalized, conversational, user-centric digital tool designed as a web application that will be integrated into the EQUICARES Policy Dashboard. Its aims is to support the mental health and well-being of people in vulnerable situations and its primary objectives are to:

- Provide user-centred mental health guidance and self-care strategies.
- Facilitate access to appropriate mental health services based on users' needs.
- Promote mental health and digital literacy.
- Collect primary data on barriers to care access through user interaction.

The Assistant will use a fine-tuned mental health-specific large language model (LLM), customized through efficient adaptation methods such as QLoRA[13], which enable high-quality results even with limited computational resources. It incorporates Retrieval Augmented Generation (RAG) to enhance contextual understanding, and includes speech-to-text and text-to-speech capabilities. The system supports multiple languages, including Romani and Arabic, to ensure broad accessibility.

The AI-based Assistant will be piloted in a **6-month non-randomised, single-group intervention study across 8 Smart Health Labs in 7 countries**. It will:

- Engage in weekly conversational interactions with participants.
- Use input from users to deliver evidence-based psychoeducational content, self-help, and coping strategies.
- Refer users to existing services based on identified needs.
- Collect self-rated assessments of mental health at pretest and post-test stages.

The Assistant will be accessible via smartphones and the project website, with special attention paid to user-friendly interfaces, particularly for elderly users or those with low digital literacy, and other specific requirements of the targeted people in vulnerable situations.

4.2 The European Approach: Ethics Guidelines for Trustworthy AI

Given the rapid evolution of AI, its regulation has become a pivotal issue in the European Union. The aim is to adopt a ‘human-centric’ AI strategy that aligns with EU values. The European Commission's 2020 White Paper on AI[14] emphasized promoting AI and addressing its potential risks. Initially, the

[13] Patil, S. S., Rathore, A. S., & Ramteke, M. (2024). QLoRA-Based Fine-Tuning of LLMs on Multiple Medical Reasoning Tasks to Enhance their Comprehension of Clinical Notes. In 2024 11th International Conference on Soft Computing & Machine Intelligence (ISCMI) (pp. 177-181). IEEE.

[14] European Commission, “On Artificial Intelligence-A European approach to excellence and trust” (White Paper, COM 65 final, 2020) 1.

Commission took a non-binding stance with its 2019 Ethics Guidelines for Trustworthy AI, crafted by the High-Level Expert Group on AI (AI HLEG). The primary goal of these guidelines is to adopt reliable AI within the EU. They are relevant because they are the initial step that influenced the creation of the AI Act draft. To support the actionability of these guidelines, the Assessment List for Trustworthy Artificial Intelligence (ALTAI) for self-assessment has also been created[15]. It provides a structured framework for organizations to evaluate and enhance the trustworthiness of their AI systems across key requirements.

The Ethics Guidelines for Trustworthy AI serve to ensure that AI is developed, deployed, and used in ways that are fair, transparent, accountable, and respect human values and rights. The framework of the guidelines is built on three essential pillars, each critical throughout the entire lifecycle of AI systems[16]:

1. **Compliance with all applicable laws and regulations.**
2. **Guiding development and use with ethical principles and values.**
3. **Demonstrating technical and social robustness to prevent unintentional harm.**

The Guidelines lay out **seven fundamental requirements** for AI systems to be considered 'trustworthy':

1. **Human agency and oversight**. To support **human agency and autonomy**, AI systems should be aimed at guiding, influencing, or supporting humans in decision-making processes, for instance, algorithmic decision support systems, risk analysis/prediction systems. AI systems should be designed to enhance human well-being, safety, and dignity. **Human oversight** is one of the seven key requirements for trustworthy AI and can be achieved through various governance mechanisms, such as 'human-in-the-loop', 'human- on-the-loop,' and 'human-in-command' approaches. Human oversight should involve human intervention at every stage of the AI lifecycle, including input data collection and use.
2. **Technical robustness and safety**. AI systems must consistently operate as intended, minimize inadvertent harm, remain resilient against adversarial attacks, and safeguard human well-being and integrity. **Resilience to attacks and security** means that the AI systems should not have adversarial, critical, or damaging effects (e.g., to human or societal safety) in case of risks or threats such as design or technical faults, defects, outages, attacks, misuse, inappropriate or malicious use. General safety aims to define the risks, risk metrics and risk levels of the AI system in each specific pilot case and identify, evaluate, and mitigate risks. **Accuracy** aims to reduce the errors produced by the AI system. **Reliability and reproducibility** mean that the AI system should perform adequately with a range of inputs and in a range of situations and show the same behaviour under similar conditions.
3. **Privacy and data governance**. This involves ensuring **privacy** and data protection throughout the entire lifecycle of the AI system, addressing data quality and integrity concerns, and implementing strict access protocols to safeguard against unlawful or unfair discrimination and ensure only qualified personnel can access individual data.
4. **Transparency**. Vital components of an AI system, such as data, the system itself, and its business models, require transparency. This includes **traceability** through well-documented data, processes, and decisions for auditing and understanding. **Explainability** is crucial for clarifying technical processes and human decisions, balancing accuracy and

[15] Assessment List for Trustworthy Artificial Intelligence (ALTAI) for self-assessment (2020). Available here: https://digital-strategy.ec.europa.eu/en/library/assessment-list-trustworthy-artificial-intelligence-altai-self-assessment

[16] EC Ethics Guidelines for Trustworthy AI, 5.

comprehensibility, especially in high-impact areas. **Communication** ensures AI systems are recognized as non-human entities, conveys their capabilities and limitations, and provides the option for human interaction when fundamental rights are at stake.

5. **Diversity, non-discrimination, and fairness**. AI systems should be designed and trained to be fair, **avoiding bias and discrimination** based on characteristics such as race, gender, age, or socioeconomic status. To comply with **Accessibility and Universal Design** requirements, AI systems should be user-centric and designed to allow all people to use AI products or services, regardless of age, gender, abilities, or characteristics. To foster trustworthiness in AI systems, organizations should **engage with stakeholders** whom the system might impact at any point in its life cycle.
6. **Societal and environmental well-being**. AI development should consider the broader environmental and societal impact, striving for sustainable and positive outcomes.
7. **Accountability**. There should be clear mechanisms in place to ensure accountability for AI systems. This involves enabling **auditability**, the reporting and minimization of negative impacts (**risk management**), addressing trade-offs between conflicting requirements, and providing accessible redress mechanisms, particularly for vulnerable individuals or groups when unjust adverse effects occur.

4.3 Ethical issues in development and deployment

4.3.1 AI-specific risks and mitigation measures

The EQUICARES AI-based assistant is envisioned as a supportive tool to enhance personalized mental health guidance, facilitate access to services, and strengthen digital and health literacy among people in vulnerable situations. Given the sensitive context and the use of personal, health-related interactions, the ethical design, development and deployment of the assistant is a key priority for the project. This section outlines the main ethical concerns related to the design, development and deployment of the assistant.

4.3.1.1. Algorithmic bias: sources, risks and mitigation

Algorithmic bias occurs when AI systems systematically favour or disadvantage certain groups. In a mental health context, biases can arise from unrepresentative training data or assumptions in algorithms, risking discrimination against vulnerable groups (e.g. minorities, people with low digital literacy). Such bias can erode trust and exacerbate inequalities. As described above, the EU's HLEG guidelines include diversity, non-discrimination and fairness as a core requirement for Trustworthy AI. Likewise, the forthcoming EU AI Act will require high-risk AI systems to use training data that is relevant, representative, and as free of errors as possible to minimize unintended bias. Even if our Assistant is not legally "high-risk", we adopt these best practices to mitigate bias:

- **Diverse & representative data:** Use inclusive training datasets from our pilot sites and "Smart Health Labs" to reflect the diversity of end-users. This helps ensure adequate representation of various vulnerable groups and mitigates bias from under-sampling. High-quality, non-discriminatory data access for training and validation is provided to avoid skewed outcomes.
- **Data augmentation and balancing techniques**: Be cautious with synthetic data generation, ensuring it doesn't introduce new biases; employ techniques (e.g. oversampling minority groups, under sampling majority groups, generating synthetic data) to balance the representation of different groups in the training data.

- **Fair algorithm design:** Incorporate fairness checks and constraints during model development. Developers should test the AI for disparate impacts across demographics and adjust models to prevent unfair outcomes. Continuous testing and re-training with new data from diverse participants will help catch biases early.
- **Inclusive co-design:** Engage stakeholders from vulnerable communities in the design and evaluation process. Their feedback can highlight biased behaviours or unintended harms. This participatory approach aligns with the project's commitment to **ethics by design**, integrating ethical values from the outset.
- **Ongoing monitoring:** Establish routines to **monitor AI outputs** for signs of bias in real deployments. The team will maintain thorough documentation and track performance metrics, enabling us to detect and correct any emerging bias or risk promptly. If, for example, the assistant's recommendations consistently underserved a particular group, developers must investigate and rectify the cause.

By proactively addressing algorithmic bias, the assistant upholds the principle of *equity* in care. This is crucial for mental health applications, ensuring no subgroup is stigmatized or left behind by AI-driven support.

The project will integrate **bias evaluation based on benchmark** with LLM observability and debugging tools to ensure fairness, equity, and principles of trustworthy AI. With this, both monitoring and mitigation of potential bias in the Assistant's outputs are possible in a continuous profile throughout development and distribution.

A structured benchmark such as the Parity Benchmark[17] will be employed to evaluate model behaviour across critical bias dimensions, including ethnicity, gender, age, physical and intellectual disability, colonial bias, and more. This benchmark provides a curated set of over 500 multiple-choice items designed to assess bias in both reasoning and factual knowledge. Evaluation using this benchmark will occur at key stages:

- Following the initial fine-tuning of the LLM
- After pilot testing and subsequent model refinement
- During major system updates and calibration efforts

The benchmark results will guide targeted mitigation strategies and ensure the model's outputs meet standards of fairness and non-discrimination.

To complement benchmark evaluations, the Assistant will be integrated with Langfuse[18], an open-source platform for observability in LLM applications. Langfuse provides:

- Real-time logging and tracing of model responses
- Debugging and inspection tools to analyze behavior across user interactions
- Custom evaluation metrics and prompt version management
- Drift detection and monitoring of performance over time

[17] Simpson, S., Nukpezah, J., Brooks, K., & Pandya, R. (2024). Parity benchmark for measuring bias in LLMs. AI and Ethics, 1-15.
[18] https://langfuse.com/

4.3.1.2. User privacy and data protection

Protecting user privacy is paramount, given the Assistant will handle sensitive health and personal data. Privacy is both an ethical obligation and a legal requirement under GDPR and medical ethics. In practice, this means adopting a **privacy-by-design** mindset: embedding data protection measures throughout development and deployment. The project adheres to *data protection by design and by default*, following industry standards (e.g. ENISA guidelines for secure development). Key privacy safeguards include:

- **Data minimisation:** Collect and use **only the data necessary** for the Assistant's functionality. In line with GDPR principles, personal data processing is limited to what is adequate and relevant for the stated purposes. For instance, if general well-being advice can be given without storing detailed medical history, no extra health details are collected.
- **Informed Consent and Control:** Ensure participants give **explicit, informed consent** for any personal data used, especially since mental health data are sensitive (special category under GDPR). Rather than a blanket consent, we implement *granular consent* options – users can choose which types of data (mood logs, chat transcripts, etc.) they are comfortable sharing. This approach empowers users and builds trust by letting them control their data sharing preferences. Participants are fully informed (via clear info sheets in their language) about the data the Assistant collects and its purpose, upholding transparency and autonomy in compliance with GDPR.
- **Anonymization & security:** Apply techniques like **pseudonymization or anonymization** to personal data wherever possible. For research data, identifiers are coded or removed so individuals cannot be readily identified. We also enforce strong security measures (encryption, secure storage) to safeguard confidentiality. By default, the system settings favor maximum privacy – for example, opt-outs are enabled unless a user opts in to data collection (reflecting "by default" principle).
- **Data management & compliance:** A comprehensive Data Management Plan (DMP) is in place to ensure GDPR alignment. It details data handling procedures, retention limits, and deletion policies. Personal data will only be retained for the period necessary for the project, then deleted or irreversibly anonymized. Regular audits of data practices are conducted to verify compliance. Developers document how data flows through the system and address any privacy risks identified (e.g. conducting a Data Protection Impact Assessment if required).

By minimizing data use and being transparent about privacy practices, we not only comply with GDPR but also foster participant trust. Users are more likely to engage with the Assistant for mental health support when they feel their personal information is respected and safe.

4.3.1.3. Transparency and explainability of automated decisions

Transparency in AI means making the Assistant's processes and decisions understandable to people. In mental health and care, transparency is vital: users and clinicians must **grasp how and why** the Assistant offers certain suggestions (e.g. recommending a coping exercise or flagging a risk) to trust and effectively use the tool. Opaque "black-box" models could confuse or even endanger users if, for example, an at-risk individual doesn't understand an automated alert. To avoid this, we emphasize **explainability and clarity** for all automated decisions. In particular:

- **Explainable AI (XAI):** The Assistant is developed with explainability in mind, aligning with HLEG's call for transparency in AI systems. Wherever feasible, we utilize algorithms that can provide interpretable outputs or explanations. The system is designed to "demonstrate

explainable AI principles", meaning its reasoning can be articulated in human-friendly terms. For instance, if the Assistant suggests a relaxation exercise, it might also convey that this recommendation is based on the user's reported stress level that day. In addition, if the suggestion is based on a specific source, the corresponding citation will be provided.

- **User-facing clarity:** All end-users will be **clearly informed that they are interacting with an AI assistant**, not a human therapist (as mandated by emerging EU AI Act transparency rules). The interface and user guides use plain language to describe the Assistant's capabilities and limits. We avoid technical jargon when communicating with users. If the system produces an output, it may include a brief explanation or a way for the user to request more information ("Why am I seeing this suggestion?"). This helps users (especially those who are vulnerable or less tech-savvy) to understand and trust the AI's support.
- **Decision documentation:** Developers will maintain detailed technical documentation for the Assistant's algorithms, training data, and decision logic. This internal transparency is required for accountability and for compliance with regulations (the EU AI Act obliges documentation for high-risk AI systems, which we proactively follow). Such documentation includes model design choices, validation results, and constraints, and it will be made available to auditors or ethical reviewers on request. It ensures that the reasoning behind AI decisions can be reviewed by experts, even if not visible to end-users in full detail.
- **Traceability & logging:** The system logs its actions and important decision points (while respecting user privacy) to create an audit trail[19]. This means if an unexpected recommendation or error occurs, the development team can trace back through the log to see what inputs and rules led to that outcome. Traceability supports both debugging and explaining outcomes after the fact. The system will include monitoring dashboards supporting real time observability, evaluations and metrics. For example, if a user reports an inappropriate response from the Assistant, logs help identify the cause (e.g. a misunderstood input) and provide an explanation or apology to the user if needed.

By making the Assistant's operations transparent and explainable, we ensure that end-users and care professionals remain informed and in control. This clarity not only complies with ethical guidelines for transparency but also enhances the Assistant's effectiveness as a collaborative tool in mental health care; users can follow its guidance with understanding, and professionals can integrate it knowing its rationale.

4.3.1.4. Accountability

Accountability is a cornerstone of ethical AI development and is especially critical in contexts involving mental health and people in vulnerable situations. EQUICARES is committed to ensuring that responsibility for the actions and outputs of the AI-based Assistant is clearly defined, traceable, and supported by effective governance mechanisms throughout its lifecycle.

To ensure accountability, EQUICARES adheres to the ethical and technical standards outlined in the EU's Ethics Guidelines for Trustworthy AI and the forthcoming AI Act, which both emphasize the importance of **traceability, auditability, and redress mechanisms**. The Assistant will be governed

[19] Audit trails are chronological records that document how a system or process operates; essentially, they track who did what, when, and how. In the context of AI systems like the EQUICARES AI-based Assistant, an audit trail helps ensure transparency, traceability, and accountability.

by internal protocols that define who is responsible for algorithmic design, testing, deployment, monitoring, and ethical evaluation, allocating clear roles for all partners involved.

Key mechanisms to operationalize accountability include:

- Audit trails and decision logs to enable review of how recommendations were generated.
- Internal ethical audits and periodic reviews overseen by WP12 and the EAB to evaluate updates and outputs to detect risks early and suggest course corrections and ensure fairness and compliance.
- Documentation protocols for AI development processes, changes, and feedback implementation.
- Error and harm response protocols, including escalation and redress channels in case of adverse effects on users.
- Transparent reporting of AI-related ethical issues in the Ethics Issue Log and Ethics Reports (D12.x series).

By embedding these accountability tools, EQUICARES aims to minimize harm, foster transparency, and uphold user trust—especially among those most at risk of marginalization or misrepresentation. This approach ensures that responsibility is not only technical but ethical and collective.

In sum, the Assistant will be developed with a precautionary, inclusive, and rights-based approach, recognising that AI in mental health is not just a technical tool but an intervention that must be ethically robust and user-centred.

4.3.2 Handling of user-generated content and potential misuse

The Assistant must be designed to safely manage user-generated input, which may include emotionally sensitive, highly personal, or distressing content. Given the mental health context and the involvement of people in vulnerable situations, ensuring that the system is neither harmful nor misleading is a top ethical priority.

User Safety and Duty of Care: Given that the EQUICARES AI-based Assistant will engage with potentially sensitive and emotional user-generated content, ensuring **user safety** is a fundamental ethical obligation. The system is designed not only to detect distress through keyword recognition but also to prioritize the **well-being of users at all times**. In cases where signs of acute distress, risk of self-harm, or disclosures of violence are detected, the Assistant will trigger predefined escalation protocols to guide users toward immediate human support services. User protection is integral to the Assistant's ethical design, reinforcing that interaction with AI must never compromise the safety or dignity of vulnerable individuals.

EQUICARES will implement a range of safeguards on the top level of the system to reduce risks associated with user interaction, content handling, and system misuse. EQUICARES will:

- **Prevent the Assistant from offering diagnosis, treatment and medication suggestions.** The system will be designed to provide general psychoeducational content and supportive guidance only, without replacing clinical judgment. Clear disclaimers will be presented to users at entry points and during relevant interactions to reinforce this boundary.
- **Use keyword recognition and distress detection** to flag input suggesting a mental health crisis or urgent safety concern. Upon detection, the system will initiate a predefined referral protocol (see Section 2.3.4), which may include prompting the user to contact emergency

services, redirecting them to professional helplines, or notifying a human operator (if applicable and consented to).

- **Prevent potential misuse**, such as impersonation, manipulation, or spam, through access and authentication mechanisms. This may include optional user verification steps, use of one-time access codes during piloting, or digital consent forms that prevent anonymous misuse while maintaining privacy.
- **Limit sensitive data retention** to avoid unintended storage of emotionally charged or personal content. User-generated messages will be anonymized or automatically deleted after processing, unless specific consent has been provided for research use.
- **Implement filters to prevent the Assistant from generating harmful or inappropriate responses.** This includes avoiding the replication of toxic language, misinformation, or triggering content by fine-tuning models with safety-aligned instructions and applying moderation layers during response generation.
- **Establish a monitoring mechanism** to identify abnormal usage patterns (e.g., repeated use with malicious intent or excessive reliance on the tool). Alerts or usage reviews will help detect and address emerging risks.
- **Empower users to report inappropriate system behaviour** through a feedback interface. This fosters shared responsibility and enables the technical team to quickly correct misaligned outputs or risks.
- **Regularly review flagged content** and interaction logs (while respecting privacy) as part of ethical oversight and incident response. The Ethics Advisory Board will be informed of any systemic misuse or recurring ethical risks that arise from user-generated content.

By embedding these content-handling safeguards and usage boundaries into the design, EQUICARES ensures that the Assistant remains a supportive, ethical, and non-harmful tool, especially for those experiencing mental distress or facing digital exclusion. All the answers of the AI system will be tracked and evaluated in real time to ensure that all the above mentioned criteria are met.

4.4 Gender dimension in AI application

This section explores how EQUICARES addresses the ethical imperative to integrate gender considerations into the design, development, and deployment of the AI-based assistant. The project acknowledges that gender is not a standalone factor, but intersects with other dimensions of identity such as age, ethnicity, and socioeconomic status. Therefore, EQUICARES adopts both gender-sensitive and intersectional approaches to ensure fairness, inclusivity, and equal access to benefits across all populations.

4.4.1 Gender analysis framework

The **EQUICARES AI-based Assistant** is being developed as an inclusive, user-centric tool to support mental health literacy, guidance, and access to services. To ensure that it promotes **gender equity** and avoids reinforcing bias or exclusion, the project integrates a **gender analysis framework** into its AI design, training, testing, and deployment processes. This approach is grounded in EU strategies for digital and gender equality, and aligns with ethical AI guidelines.

Gender-Sensitive Design and Development

From the earliest stages of development, the Assistant is designed to recognise and respond to the diverse needs and experiences of users of different genders, including women, men, transgender, non-binary, and gender-diverse individuals. This includes:

- Gender-inclusive data sourcing: Datasets used to train and test the Assistant are reviewed to ensure they are representative across gender identities, avoiding overrepresentation of male or binary-only data.
- Gender-sensitive natural language processing: The Assistant is designed to avoid gendered assumptions or stereotypical phrasing, and to use inclusive language that affirms diverse identities.
- Personalisation options: Users can self-identify their gender and preferences during interaction to tailor tone, content, and responses in a respectful and affirming way.

Gender-Aware Testing and Evaluation

During testing, EQUICARES applies a gender lens to evaluate whether the Assistant:

- Delivers comparable levels of support and accuracy across different genders.
- Uses language and content that is free from bias or stereotypes.
- Recognises and adapts to gendered patterns of digital use, such as comfort with AI, device access, or health-seeking behaviours.

The testing process includes:

- Disaggregated user feedback collection by gender.
- Simulation of gender-specific scenarios in emotional support and care navigation.
- Bias detection audits to check for any disparities in the Assistant's performance or responsiveness across genders.

Integrating Intersectionality in Gender Analysis

Gender does not operate in isolation. The Assistant's ethical development is informed by an intersectional framework, recognising that gendered experiences differ significantly across other identity dimensions such as race and ethnicity, age (e.g., elderly women, adolescent boys), disability status, migration or refugee background, sexual orientation. Therefore, the Assistant is co-designed and tested in collaboration with users from intersecting identities, ensuring it responds not only to gender but also to compounded vulnerabilities and social exclusion.

Application to Ethics-by-Design

The EQUICARES Assistant applies this gender framework as part of its ethics-by-design methodology, with technical and ethical teams working jointly to:

- Regularly audit algorithmic outputs for gender bias
- Integrate feedback loops to identify and address gender-related issues in real time
- Adapt UI/UX to ensure equal access and comfort for all gender identities

This framework contributes to the Assistant's trustworthiness, fairness, and ethical compliance, ensuring that it does not reinforce social inequalities but instead actively promotes gender-responsive mental health support.

⚠ User Safety Comes First

The Assistant must always act with user safety and dignity as its highest priority. Any indications of distress, crisis, or harm must trigger immediate escalation to human support channels.

4.5 AI Impact assessment

The following table presents a structured impact assessment, including risks and mitigation measures, of the AI-based Assistant developed in EQUICARES, based on the key ethical and technical risks identified above. It outlines each risk's potential impact, severity, and specific mitigation measures, along with the responsible work packages or actors overseeing ethical compliance.

Table 13.Ethical impact assessment of the AI-based Assistant.

Risk category	Specific risk	Potential impact	Risk severity	PVS affected	Mitigation measures	Responsible WP / partners
Algorithmic bias	Discriminatory outputs due to biased training data	Unfair treatment of vulnerable groups; loss of trust	High	All vulnerable groups	Use diverse datasets; conduct fairness audits; involve end-users in design	WP3, WP4, WP12
Privacy & data protection	Unauthorised access or misuse of personal/sensitive data	Legal non-compliance; harm to user privacy and trust	High	All users	Apply privacy-by-design; encrypt data; get explicit, informed consent	WP3, WP12
Transparency	Users do not understand how or why the Assistant gives recommendations	Misuse, loss of confidence, refusal to engage	Medium	All users	State AI nature clearly; provide explainable outputs and user guidance	WP3, WP4, WP12
Multimodal transparency	Users cannot interpret audio-generated content or miss disclaimers	Reduced trust; increased misunderstanding	Medium	Low-literacy users, older people, non-native speakers	Audio cues with simplified logic; subtitles; reinforcement through text	WP3, WP4
Human oversight	Lack of human-in-the-loop during critical moments or misalignment of escalation protocols	Risk of inadequate response in emotionally sensitive scenarios,	Medium	PVS in distress	Maintain escalation protocols; design real-time human fallback options	WP3, WP4, Pilot partners?
Misuse or overreliance	Users perceive the Assistant as a diagnostic tool or emergency service	Risk of harm from misinterpretation or lack of appropriate referral	High	General users, especially vulnerable individuals	Display disclaimers; provide escalation paths to human support	WP3, WP4, Pilot partners
Inaccurate outputs	AI provides outdated, incorrect, or inappropriate responses	Misinformation, reduced effectiveness, ethical concern	Medium	All users	Update models regularly; collect and analyse feedback	WP3, WP4, EAB
Security / cyber Risk	Cybersecurity breach or manipulation of the Assistant	Compromise of data, user safety, and system integrity	High	All users	Follow ENISA secure dev guidelines; audit and test security	WP3, WP12
Lack of user inclusiveness	Inaccessible design for low-literacy or linguistically diverse users	Exclusion and reduced engagement by key user groups	Medium	Low-literacy users, migrants, elderly	Design for plain language, multilingual use, and audio/visual support	WP3, WP4, Pilot partners
Accountability gap	Unclear responsibility for AI errors or ethical issues	Delayed response to harms or unresolved ethical risks	High	Project-wide responsibility	Assign clear ethical roles; log decisions; audit and report issues	WP3, WP12, EAB

Gender bias in data	Training data underrepresents or misrepresents gender-diverse individuals	Marginalisation of gender-diverse users; reduced trust	High	Gender-diverse users	Ensure balanced datasets; validate inclusivity; consult gender experts	WP3, WP12
Discriminatory outputs	AI provides recommendations that reinforce gender stereotypes	Reinforcement of harmful gender norms; reduced credibility	High	Women and gender-diverse individuals	Use inclusive, neutral language; test responses across gender groups	WP3, WP4
Gendered barriers to access	AI tools are less accessible to women due to tech/literacy barriers	Reduced uptake/effectiveness among women and girls	Medium	Women, girls, caregivers	Design UI to support accessibility; adapt to tech literacy differences	WP3, Pilot partners
Invisibility of non-binary and trans identities	AI fails to recognise or adapt to trans and non-binary identities	Misgendering or exclusion; emotional harm and disengagement	High	Trans and non-binary users	Allow gender self-identification; avoid binary default settings	WP3, WP4
Lack of intersectional sensitivity	AI overlooks the needs of multiply marginalised users	Unequal outcomes; needs of marginalised groups overlooked	Medium	Intersecting identities (e.g. Roma women, disabled youth)	Apply intersectional analysis; involve diverse co-design groups	WP3, WP4

5. Ethics Governance and Oversight in EQUICARES

Ethical governance in EQUICARES is a central pillar of the project's implementation, particularly given the sensitivity of working with PVS, and the development and deployment of an AI-based Assistant for mental health support. As such, EQUICARES has established a robust ethics oversight framework designed to ensure ongoing ethical compliance across all project activities, involving the establishment of an Ethics Advisory Board (EAB) and the appointment of an external Ethics Advisor (EA).

5.1 Ethics Advisory Board

The Ethics Advisory Board (EAB), also mentioned as the Ethical Committee of the project, plays a central role in ensuring that the EQUICARES project adheres to the highest ethical standards across its research and implementation activities. Appointed in the first month of the project (M1), the EAB is responsible for addressing emerging ethical challenges, providing expert guidance, and ensuring ethical compliance. Detailed information about the members of the EAB, their CVs, and relevant documentation is presented in the deliverable *D12.1 - OEI - Requirement No. 1*[20], submitted in M1.

Comprised of three renowned experts, the EAB brings diverse expertise in research ethics, mental health governance, pharmacology, and youth service evaluation. The EAB will gather annually and as needed in ad hoc instances to review and oversee the annual ethical audits conducted by each partner, and the implementation of the Ethics Handbook throughout the project's duration. It will also provide ad hoc guidance by delivering ethics training to consortium partners, whenever necessary, such as for example gender sensitization.

The EAB's work extends across several key deliverables (D9.3, D10.3, and D12.1-5) and is critical to fostering transparency, integrity, and responsible research practices. By providing a structure for ethical reflection and guidance, the EAB ensures that EQUICARES not only complies with formal obligations but also upholds the dignity and rights of all participants.

5.2 External Ethics Advisor

In addition to the EAB, EQUICARES appointed an independent External Ethics Advisor (EA), to further strengthen ethical oversight. Their appointment responds to requirements set by the European Commission's Ethics Summary Report and focuses specifically on data protection, research involving vulnerable groups, and AI-driven tools. Detailed information about the EA, their CVs, and relevant documentation is presented in *D12.2 – H - AI - POPD - Requirement No. 2*[21].

The EA is a lawyer with over 25 years of experience in data protection, research ethics, and technology law. Their role encompasses advisory, monitoring, and reporting duties. They review all

[20] The document is defined as containing sensitive information, and thus, personal information is not disclosed in this report.
[21] The document is defined as containing sensitive information, and thus, personal information is not disclosed in this report.

ethics-related procedures, provide strategic input on high-risk issues such as informed consent and incidental findings, and support the preparation of documents like data protection policies and informed consent forms. They submit periodic ethics reports to the Commission (M18, M36, M48), aligning their oversight with the reporting cycles of the project.

The EA's independence is formally safeguarded through a Declaration on Conflict of Interest and a Memorandum of Understanding signed with the coordinator. Their involvement enhances EQUICARES' capacity to anticipate, detect, and mitigate ethical risks in a timely and expert-driven manner, ensuring compliance and fostering ethical innovation.

5.3 Roles and responsibilities

The ethical governance structure of EQUICARES comprises both internal (EAB) and external (EA) oversight mechanisms, with clearly defined and complementary roles:

Ethics Advisory Board (EAB):

- Overseeing adherence to the Ethics Handbook throughout the project's duration.
- Gathering annually and as needed in ad hoc instances to address emerging ethical challenges and ensure continuous compliance with ethical standards.
- Providing guidance and insights into ethical issues and decision-making processes.
- Informing and educating all consortium partners regarding ethical issues to ensure a thorough understanding of ethical responsibilities and support ethical awareness and compliance.
- Reviewing the reports and assessing compliance with ethical standards and identifying any areas of concern or improvement.

External Ethics Advisor (EA):

The role of the independent Ethics Advisor is to advise and assist the consortium in understanding and appropriately addressing the ethics issues raised by the project activities. More specifically:

- Monitoring the aims, objectives, methodology, and implications of the research activities to ensure adherence to the highest ethical standards.
- Providing guidance, advice, monitoring, and recommendations for project activities in a facilitative manner.
- Attending relevant project meetings, whether virtual or face-to-face, to track project progress and preparing comprehensive reports after each meeting for the project management team, when and if necessary, that should include independent summaries of discussions and highlight any arising issues, if necessary.
- Collaborating with consortium members to prepare three periodic reports. The first report should be submitted in Month 18 (M18) of the project, followed by two additional reports aligned with the project reporting periods. More specifically, the three reports are: (i) Deliverable D12.3 – POPD – H - AI - NEC - Requirement No. 3 (M18); (ii) Deliverable D12.4 – AI - NEC - POPD - H - Requirement No. 4 (M36); and (iii) Deliverable D12.5 – H - POPD - NEC - AI - Requirement No. 5 (M48).
- Assisting in the preparation of authorisations, approvals, informed consent forms, and the Personal Data Protection Policy for the project, among other related tasks.
- Reviewing specific project deliverables, as well as the project's mid-term and final reports

As coordinator of WP12, White Research (WR) plays a facilitative and enabling role within the EQUICARES ethics governance framework. In particular, WR coordinates the activities of the EAB, ensuring its smooth operation and the timely organisation of meetings, trainings, and ethics-related discussions. It also maintains regular communication with the EA to align project activities with external guidance. While WR does not directly carry out ethical reviews or assessments, it serves as a central point for coordinating inputs, circulating key documents, supporting partners in ethics-related processes, and responding to ad hoc requests for clarification or support from consortium members or ethics governance bodies. Together, the EAB and EA ensure EQUICARES not only complies with ethical standards but also contributes to the development of robust, inclusive, and responsible research practices.

5.4 Ethics review & approval procedures at the pilot sites

To ensure ethical compliance of the research and intervention activities involving human participants, ethical approval from relevant local/national committees have to be obtained before conducting any research activity with humans. In the case of EQUICARES pilot partners, while some of them have local/organisational ethics committees for review & approval of applications, others do not currently have such procedures in place, as shown in Table 14. In these cases, external ethical approval from national or regional ethics committees will be pursued, particularly for activities involving primary data collection from PVS. Coordination for such processes will be supported by the Ethics Advisory Board (EAB), as well as by the Ethics Advisor.

Table 14 Ethical approval processes for pilot partners.

Partner	Country	Ethics Policy	Institutional Ethics Committee	External Committee Available
SEERC	Thessaloniki Greece	**Yes**	Yes, Psychology Department Ethics Committee (University of York Europe Campus, Thessaloniki)	Not applicable
GIVMED	Athens Greece	**No**	Not applicable (not conducting academic research)	Possibly needed; has Code of Conduct
FISEVI	Sevilla Spain	**Yes**	Not applicable (not conducting academic research)	**External**: Andalusian Committee of Bioethics
ZI	Germany	**Yes**	Yes, Ethics Committee II of University of Heidelberg Medical Faculty Mannheim	Not applicable
LGBTI	Ireland	**No**	No. Previously applied through partner organisations; currently exploring options	Exploring alternatives (e.g., JIGSAW)
Koc University	Türkiye	**Yes**	Yes, Koc University Ethical Committees	Not applicable
LADAPT	France	**No**	Not applicable (not conducting academic research)	To be explored
AMALIPE	Bulgaria	**Yes**	Not applicable (not conducting academic research)	To be explored

The kick-off meeting of the EQUICARES Ethics Advisory Board (EAB) with the coordination team (WR) took place in March 26th, 2025 and several recommendations were made regarding the ethics approval processes for the project's research and pilot activities. It was underlined that all pilot partners are required to secure ethics approval for their pilot activities from relevant local/national ethics committees. The approval process is recommended to be carried out in two distinct rounds:

1. The first round should specifically address WP1 activities, particularly Tasks 1.4 and 1.5, which involve human participants.
2. The second round of approvals will focus on pilot interventions described in WP3 and WP4.

Additionally, the EAB emphasised the importance of flexibility in ethical approvals, acknowledging that the specific nature of pilot activities may vary significantly depending on target populations and locations. This flexibility will ensure ethical compliance while accommodating the nuances and particularities of each pilot context. As an additional support tool, the **European Network of Research Ethics Committees (EUREC)**[22] database of national research ethics structures and procedures across Europe will be a valuable resource for pilot partners navigating their local ethics requirements and identifying the relevant ethics review bodies.

5.5 Ethical oversight and compliance

To ensure continuous ethical compliance across the EQUICARES project, a set of internal processes has been established. These mechanisms include an **Annual Ethical Audit**, an **Ethical Issue Log**, and an **Incidental Findings Log**, designed to systematically monitor, document, and address ethical considerations arising throughout the project's lifecycle. These processes enable timely identification and management of ethical challenges, ensuring transparency, accountability, and ongoing improvement.

Annual ethical audits: All consortium partners will be responsible for conducting annual ethical audits. This audit:

- Describes the implementation of ethical processes within each partner's respective activities.
- Reports on the handling of informed consent, data protection, and inclusion of vulnerable populations.
- Flags any ethical issues, incidents, or deviations from planned procedures.

Audits will be collected and reviewed by the EAB, which will assess each partner's compliance and provide tailored feedback or recommendations for improvement. The Ethical Audit template can be found in Annex 8.2.

To support continuous ethical monitoring, two log templates are also available to all partners:

- **Ethical Issue Log**: for reporting and tracking any ethical concerns, dilemmas, or breaches that arise during implementation. The relevant template can be found in Annex 8.1.
- **Incidental Findings Log:** for documenting unexpected findings that may have implications for participant well-being and may require referral, support, or ethical consultation. The relevant template can be found in Annex 8.3.

Both logs are maintained internally and reviewed periodically by the EAB and WP12 leader (WR) to ensure appropriate follow-up and collective learning.

[22] https://eurecnet.eu/recs-in-europe/

Finally, all EAB meetings, whether annual or ad hoc, will result in a short summary of recommendations, shared with the consortium. These may relate to:

- Adjustments in methodology due to ethical considerations.
- Updates to informed consent procedures or data handling.
- Need for further ethical approval or consultation.
- Systemic issues such as bias or accessibility.

The recommendations will be integrated into the ongoing ethics monitoring and will inform the final update of the Ethics Handbook D10.3, due in M24 (December 2026).

6. Conclusions

This handbook provides comprehensive ethical guidance tailored explicitly for EQUICARES research and pilot activities involving people in vulnerable situations and the AI-based Assistant. It highlights the project's commitment to ethical research conduct, inclusive practices, and the responsible and ethical deployment of AI technologies.

Key ethical principles underscored in this document include respect for human dignity, informed consent, privacy protection, transparency, accountability, non-discrimination, and equity—principles deeply aligned with EU and international ethical standards. Particular emphasis is placed on addressing the unique vulnerabilities and specific ethical considerations relevant to diverse groups, such as LGBTQIA+ individuals, people with disabilities, migrants, refugees, ethnic minorities, older adults, and youth.

The handbook also details how gender-sensitive methodologies and intersectional frameworks will be integrated into all stages of research and AI development to ensure fairness, inclusivity, and the equitable representation of diverse identities. Additionally, comprehensive strategies are outlined to mitigate AI-specific ethical risks, including algorithmic bias, lack of transparency in automated decision-making, user privacy concerns, and potential misuse of user-generated content.

A robust governance structure, led by the Ethics Advisory Board (EAB), ensures ongoing ethical oversight and compliance. Annual ethical audits conducted by consortium partners serve as proactive mechanisms to identify and address ethical issues systematically, complemented by internal tools such as the Ethical Issue Log and the Incidental Findings Log. These structured processes foster transparency and accountability across the consortium, providing continuous feedback loops and mechanisms for rapid corrective actions when ethical concerns arise.

As project activities advance, the handbook will have an updated version (D10.3 due in M24 – December 2026), incorporating lessons learned and emerging best practices from the field and pilot interventions. Through this iterative process, EQUICARES will maintain ethical integrity and responsiveness, continuously enhancing the ethical robustness of project activities.

7. References

ALLEA – All European Academies. (2017/2023). The European Code of Conduct for Research Integrity. Revised edition. Berlin: ALLEA. https://allea.org/code-of-conduct/

Assessment List for Trustworthy Artificial Intelligence (ALTAI) for self-assessment (2020). Available here: https://digital-strategy.ec.europa.eu/en/library/assessment-list-trustworthy-artificial-intelligence-altai-self-assessment

American Psychological Association - APA. (2015). *Guidelines for Psychological Practice with Transgender and Gender Nonconforming People.* https://www.apa.org/practice/guidelines/transgender.pdf

Council of Europe. (1995). *Framework Convention for the Protection of National Minorities*. Strasbourg: Council of Europe. https://www.coe.int/en/web/minorities

Council of Europe (2011). *Istanbul Convention on preventing and combating violence against women and domestic violence.* https://www.coe.int/en/web/istanbul-convention

Council of Europe. (2014). *Recommendation CM/Rec(2014)2 of the Committee of Ministers to member States on the promotion of the human rights of older persons*. Strasbourg: Council of Europe. https://rm.coe.int/16806f1ffc

European Commission. (2005). *The European Charter for Researchers and The Code of Conduct for the Recruitment of Researchers*. Luxembourg: Office for Official Publications of the European Communities. https://euraxess.ec.europa.eu/jobs/charter

European Commission. (2018). *EU Youth Strategy 2019–2027: Engaging, Connecting and Empowering Young People*. Luxembourg: Publications Office of the European Union. https://ec.europa.eu/youth/policy/youth-strategy_en

European Commission. (2020). *Gender Equality in the European Research Area*. https://ec.europa.eu/info/research-and-innovation/strategy/strategy-2020-2024/democracy-and-rights/gender-equality-research-and-innovation_en

European Commission. (2021). *Union of Equality: Strategy for the Rights of Persons with Disabilities 2021–2030*. Luxembourg: Publications Office of the European Union. https://ec.europa.eu/social/main.jsp?catId=1484&langId=en

European Institute for Gender Equality - EIGE. (2016). *Gender-sensitive and inclusive communication.* https://eige.europa.eu/publications/gender-sensitive-communication

EU Agency for Fundamental Rights - FRA (2020). *Trauma and support for victims of crime in the EU.* https://fra.europa.eu/en/publication/2020/trauma-support-victims-crime-eu

Fassin, D. (2001). The biopolitics of otherness: Undocumented foreigners and racial discrimination in the French public health system. *Anthropology Today*, 17(1), 3-7. https://doi.org/10.1111/1467-8322.00056

International Committee of Medical Journal Editors (ICMJE). *Recommendations for the* Conduct*, Reporting, Editing, and Publication of Scholarly Work in Medical Journals*. Updated 2023. https://www.icmje.org/recommendations/

Patil, S. S., Rathore, A. S., & Ramteke, M. (2024). QLoRA-Based Fine-Tuning of LLMs on Multiple Medical Reasoning Tasks to Enhance their Comprehension of Clinical Notes. *In 2024 11th International Conference on Soft Computing & Machine Intelligence* (ISCMI) (pp. 177-181). IEEE.

Simpson, S., Nukpezah, J., Brooks, K., & Pandya, R. (2024). Parity benchmark for measuring bias in LLMs. AI and Ethics, 1-15.

UNESCO. (2003). *Recommendation concerning the Promotion and Use of Multilingualism and Universal Access to Cyberspace*. Paris: United Nations Educational, Scientific and Cultural Organization. https://unesdoc.unesco.org/ark:/48223/pf0000129728

United Nations. (2006). *Convention on the Rights of Persons with Disabilities (CRPD)*. New York: United Nations. https://www.un.org/development/desa/disabilities/convention-on-the-rights-of-persons-with-disabilities.html

United Nations office for Disaster Risk Reduction - UNDRR (2025). *Sendai Framework Terminology on Disaster Risk Reduction*, https://www.undrr.org/terminology/vulnerability

World Health Organization – WHO (2015). *Global Standards for Quality Health-Care Services for Adolescents: A Guide to Implement a Standards-Driven Approach to Improve the Quality of Health-Care Services for Adolescents*. Geneva: WHO. https://www.who.int/publications/i/item/9789241549332

World Health Organization - WHO (2025). *Vulnerability and vulnerable populations*. https://wkc.who.int/our-work/health-emergencies/knowledge-hub/community-disaster-risk-management/vulnerability-and-vulnerable-populations

8. Annexes

8.1 Ethics issue log template

- *To be filled in only when a significant ethical or safety-related issue arises at any stage of the project activities (planning, implementation, etc.)*
- *This log is stored securely and should not contain personally identifiable information.*
- *Logs will be submitted periodically (e.g., quarterly or before key reviews) to the Ethics Committee for monitoring and advisory support.*

Field	Details
Issue ID	[Number id]
Description of ethical concern	[Describe what is the issue: e.g. lack of internal process for ethical approval of research and pilot activities]
Category	[e.g., WP1 – Task 1.5]
Priority	[Low / Medium / High / Critical]
Impact	[Low / Medium / High]
Task Leader	[Partner name]
Work Package Leader	[Partner name]
Date identified	[DD/MM/YYYY]
Due date	[DD/MM/YYYY]
Status	[Open / Closed]
Actions to be taken	[Describe what actions have to be taken]
Notes	[Optional: reflections, lessons learned, recommendations]

8.2 Ethical Audit template

- *To be filled annually by all consortium partners, who will be responsible for conducting them.*
- *To be collected and monitored by the Ethical Committee which will review the reports and assess compliance with ethical standards and identify any areas of concern or improvement.*

Section 1: Partner Identification

Partner Name	
WP(s) and Task(s) Covered	
Reporting period (e.g. M1–M12)	
Date of audit submission	

Section 2: Overview of activities

Brief summary of the partner's activities during the reporting period, highlighting any that involved:
- Research with human participants
- Use of AI tools or digital platforms
- Engagement with vulnerable populations

Max 300 words

Section 3: Implementation of ethical principles and guidelines

Ethical Area	**Yes / No**	Description of implementation (if No, explain why not or provide plan to address)
Has an ethics review or approval been obtained for this task? (If yes, specify by whom and attach proof)		
Is informed consent obtained from all participants?		
Are there procedures in place to ensure data privacy and security?		
Are incidental findings anticipated? If yes, make sure to use also the incidental finding template to report it.		
Have all team members been informed about the ethical considerations and guidelines of EQUICARES?		
Are measures taken to ensure inclusive, accessible, and culturally appropriate engagement with participants?		

If the task involves AI-based tools, have bias mitigation and transparency measures been implemented?		

Section 4: Ethical Issues or Challenges Encountered

- Describe any ethical dilemmas, challenges, or incidents encountered during the reporting period.
- Include how they were addressed or escalated, and lessons learned.
Max 300 words Max 300 words

Section 5: Additional comments

Please describe any challenges, lessons learned, or support needed.

Section 6: Supporting documents

Please attach any relevant documentation (e.g. consent forms, ethics approvals, etc.).

Confirmation

☐ I confirm that the information provided in this report is accurate and reflects the ethical practices of our organisation within the EQUICARES project.

Signature: _____ Date: _____

8.3 Incidental findings log template

- *To be filled in only when a significant ethical or safety-related issue arises during research or engagement activities.*
- *This log will be stored securely and should not contain personally identifiable information.*
- *A separate, confidential referral form may be used by local teams (if needed) but should not be included in this log.*
- *Logs will be submitted periodically (e.g., quarterly or before key reviews) to the Ethics Committee for monitoring and advisory support.*

Field	Details
Date of Incident	[DD/MM/YYYY]
Pilot Site / Country	[e.g., Spain / Ireland / Greece]
Work Package / Task	[e.g., WP1 – Task 1.5 Fieldwork]
Type of Activity	[e.g., Interview / Workshop / Survey / Observation / AI-based interaction]
Brief Description of the Finding	[Objective and concise summary; avoid identifiable details. E.g., participant disclosed suicidal ideation, signs of acute distress, suspected abuse, etc.]
Immediate Action Taken	[Describe in detail what was done: paused activity, provided support, made warm referral, etc.]
Was Referral Initiated?	[Yes / No]
If Yes, Referral Details	[To whom? When? Type of service or support? E.g., local psychologist, community health center]
Participant Consent Maintained?	[Yes / No / N/A – briefly explain if withdrawn]
Follow-up Needed?	[Yes / No – and what kind? E.g., EAB/EA input, pilot lead update]
Notes or Observations	[Optional: reflections, lessons learned, recommendations]
Logged By (Initials & Role)	[e.g., AP – Field Researcher]
Date Logged	[DD/MM/YYYY]

equicares

COMMUNITY-DRIVEN INCLUSIVE, EQUITABLE, MENTAL HEALTHCARE ACCESS

GA 101156500

PARTNERS

WHITE

university of groningen

Erasmus School of Health Policy & Management

KOÇ ÜNİVERSİTESİ

SEERC SOUTH-EAST EUROPEAN RESEARCH CENTRE

GIVMED Share medicine Share life

AMALIPE Center For Interethnic Dialogue and Tolerance

LADAPT

LGBT IRELAND For Inclusion For Equality For Everyone

FISEVI Fundación para la Gestión de la Investigación en Salud de Sevilla

Zentralinstitut für Seelische Gesundheit

Q-PLAN INTERNATIONAL

JIGSAW Young people's health in mind

EHTEL Collaborating for Digital Health and Care in Europe

diesis network

EUCOMS The European Community based Mental Health Service Providers Network www.eucoms.net

EASPD European Association of Service providers for Persons with Disabilities

SQUAREDEV

Funded by the European Union