EYE-TEACH

Deliverable 4.2

Ethical Framework and Guidelines

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Executive Summary

This deliverable D4.2 presents the development, implementation, and application of the EYE-TEACH Research Protocol Template, an internal tool designed to support ethical, legal, and data protection compliance across all experimental studies involving human participants within the project. Building on the regulatory and ethical frameworks analysed in Deliverable D4.1, the template operationalises key principles, such as informed consent, risk minimisation, data protection, and responsible AI development, into a structured and practical instrument for researchers.

The deliverable is organised into two main parts. The first one describes the structure, rationale, and development process of the template, highlighting its grounding in an ethics and privacy by design approach and its iterative refinement through collaboration with project partners and the Ethics and Legal Advisory Board (ELAB). The second part provides a systematic analysis of the completed templates, focusing on the most relevant ethical and legal aspects of the experimental studies conducted within the project. This analysis highlights both strengths and areas for improvement, including recurring issues such as the distinction between anonymisation and pseudonymisation, the adequacy of data security measures, the role of Data Protection Impact Assessments (DPIAs), and the ethical management of research involving minors and school settings. These insights contribute to the ongoing monitoring of the project's ethical and legal sustainability and will inform the final recommendations.

Importantly, the Research Protocol Template is included as an Annex to Deliverable D4.2, which has a public dissemination level. By contrast, Deliverable D7.1, classified as sensitive and forming an integral part of D4.2, contains the completed templates submitted by project partners, together with the relevant supporting materials, where available.

Introduction

The EYE-TEACH project aims to develop an AI-assisted eye-tracking (ET) analytics tool to support teachers in understanding students' reading processes and improving educational outcomes. By combining insights from cognitive science, educational research, and artificial intelligence, the project adopts a human-centred and evidence-based approach to the design and validation of innovative educational technologies. Within this framework, Work Package 4 (WP4) is dedicated to ensuring that all project activities comply with the highest ethical, legal, and data protection standards, with particular attention to the involvement of human participants, including children, and the responsible development of AI systems.

Deliverable D4.2 represents a key outcome of WP4 and builds upon the foundations established in Deliverable D4.1, where the relevant European ethical and legal frameworks were analysed. The main objective of D4.2 is to operationalise these principles through the development, implementation, and application of a structured Research Protocol Template, designed to guide project partners in planning and documenting experimental studies involving human participants. In addition, the deliverable provides a systematic analysis of the information collected through the completed templates, with the aim of supporting partners in identifying and addressing potential ethical and legal issues at an early stage, and of ensuring the overall ethical and regulatory sustainability of the project.

The deliverable is organised into two main parts. The first part presents the structure and rationale of the Research Protocol Template, explaining how its questions and sections reflect key ethical principles and legal requirements, including those derived from the General Data Protection Regulation (GDPR) and emerging AI governance frameworks, such as the AI Act. The second part focuses on the analysis of the completed templates submitted by the Principal Investigators of the experimental studies conducted within the project. It includes: (i) an overview of the main characteristics of the studies; (ii) a targeted ethical and legal assessment of each study, based on both Section A (Research Ethics and Ethics of AI) and Section B (Data Protection and AI Risk Classification); and (iii) the identification of common ethical, legal, and data protection issues across studies, discussed in light of relevant European guidelines and regulations.

The Research Protocol Template lies at the core of this deliverable. It has been developed as a practical and reflective tool to support researchers in systematically considering the ethical and legal implications of their work. Its structure reflects a clear distinction, while maintaining their interconnection, between ethical aspects (Section A) and legal/data protection aspects (Section B). The template was created through an iterative and participatory process involving project partners and the Ethics and Legal Advisory Board (ELAB). Following an initial version shared within the consortium, feedback from researchers led to substantial revisions, including improvements in clarity, usability, and alignment with the practical needs of different study designs. The final version (v2.1) is currently adopted across the project. Importantly, the template is not intended to replace formal ethics approvals or legally required documentation, but rather to facilitate their preparation, promote internal consistency, and enhance transparency.

The application of the template to the experimental studies conducted within EYE-TEACH has produced several important results. First, it has enabled a systematic mapping of ethical and legal considerations across diverse study designs, ranging from survey-based research with teachers to experimental eye-tracking studies involving children. Second, it has supported researchers in identifying potential issues, such as the handling of personal and biometric data, informed consent procedures, risk assessment, and the future implications of AI system development, before the submission to institutional ethics committees. Third, it has highlighted a number of cross-cutting themes, including the need for greater clarity on data anonymisation versus pseudonymisation, the importance of robust security measures, the role of Data Protection Impact Assessments (DPIAs), and the ethical challenges associated with research involving children in school settings. These findings demonstrate that the template not only functions as a reporting tool but also as a capacity-building instrument, fostering ethical awareness and supporting a shared understanding of legal obligations within the consortium. At the same time, the analysis has identified areas where further clarification, alignment, or improvement may be beneficial, particularly for studies that are still in the planning phase. The work presented in this deliverable represents an important step in an ongoing process. Further iterations of the template and continued exchanges with project partners are planned, especially for upcoming studies within WP2 and for activities related to the development and testing of the AI system in WP3. In addition, the insights gained from the ongoing and future analysis of the completed templates will inform the development of final ethical

and legal recommendations to be delivered at the end of the project, contributing to a coherent and sustainable framework for responsible research and innovation in educational AI.

Finally, while the Research Protocol Template is included as an annex to this Deliverable D4.2, the completed templates submitted by the project partners are collected in Deliverable D7.1, which forms an integral part of the overall documentation. The two deliverables should therefore be read in conjunction, as they respectively provide the methodological framework and the empirical basis for the ethical and legal assessment conducted within WP4.

Methodology for the Development and Completion of the Research Protocol Template

This section describes the methodological approach adopted for the development and implementation of the EYE-TEACH Research Protocol Template, a core internal tool designed to assess that all experimental activities involving human participants within the project are conducted in compliance with the highest ethical, legal, and scientific standards.

Ethics and Privacy by Design Approach

The development of the Research Protocol Template was grounded in an ethics and privacy by design approach, which represents a proactive and anticipatory strategy for addressing ethical and legal challenges in research involving human participants and artificial intelligence (AI).

Rather than treating ethical and data protection requirements as ex post compliance obligations, the EYE-TEACH project integrates them from the earliest stages of research design and implementation. This approach is particularly relevant given the nature of the project, which involves the collection and analysis of sensitive data, especially eye-tracking data, from human participants, including minors, in educational contexts.

The ethics and privacy by design framework adopted in EYE-TEACH is based on three core principles:

- Proactivity and anticipation: ethical and legal risks are identified at an early stage of each study, before data collection begins. This includes risks related to participant well-being, informed consent, algorithmic bias, and data protection.
- Integration into research design: ethical reflection is embedded directly into the scientific and methodological planning of each study. Researchers are required to justify their choices not only in terms of scientific validity but also in terms of ethical acceptability and proportionality.
- Collaborative mitigation strategies: the identification and mitigation of risks are carried out in close collaboration between the scientific partners conducting the studies and the CNR ethics team. This collaborative process enables the co-development of context-sensitive solutions tailored to the specific characteristics of each experimental activity.

Through this approach, the Research Protocol Template functions not only as a reporting tool but also as a reflexive instrument, encouraging researchers to systematically consider the ethical and legal implications of their work and to adopt appropriate safeguards throughout the research lifecycle.

Normative and Ethical Frameworks

The design of the Research Protocol Template was informed by a comprehensive review of the main European ethical and legal frameworks governing research involving human participants, data protection, and the development and use of artificial intelligence. These frameworks were analysed in detail in Deliverable D4.1 and have been operationalised within the structure and content of the template. Key reference frameworks include:

- European guidelines *Ethics in Social Science and Humanities Research* (2021), which provide principles and practical guidance for conducting ethically responsible research involving human participants, with particular attention to informed consent, risk assessment, and the protection of vulnerable groups.
- The *General Data Protection Regulation* (GDPR, 2016), which establishes the legal framework for the processing of personal data within the European Union,

including principles such as lawfulness, transparency, purpose limitation, data minimisation, and the protection of data subject rights.

- The *Ethics Guidelines for Trustworthy AI* (2019) developed by the European Commission, which define key requirements such as transparency, fairness, accountability, and human oversight in the design and use of AI systems.
- The *Artificial Intelligence Act* (AI Act, 2024), which introduces a risk-based regulatory approach to AI systems and is particularly relevant for assessing the classification and potential impact of AI tools developed within the project.

These regulatory and ethical references have been translated into operational requirements and guiding questions within the template, so that each experimental study systematically addresses both ethical considerations (e.g., participant protection, fairness, and research integrity) and legal obligations (e.g., data protection, consent for data processing, and AI risk classification).

Internal Development Process of the Template

The Research Protocol Template was developed through an iterative and participatory process, designed to capture the specific needs and challenges of the EYE-TEACH project. The first version of the template (v1) was drafted by the CNR team and shared with all project partners on 20 December 2025. This initial version aimed to provide a comprehensive structure for documenting the scientific background and robustness, methodologies, and ethical and legal aspects of experimental studies involving human participants. Following its dissemination, partners were invited to provide feedback based on their disciplinary perspectives, methodological approaches, and anticipated experimental activities. This feedback was instrumental in identifying areas where the template required clarification, simplification, or further alignment with the practical needs of researchers.

Based on this feedback, a major revision (v2) of the template was developed. One of the most significant improvements introduced in this version was the clear separation between ethical and legal dimensions, resulting in the division of the template into two main sections:

- Section A: Research Ethics and Ethics of Artificial Intelligence, focusing on ethical principles for the involvement of research participant, and the responsible development and use of AI;

— Section B: Data Protection and AI Risk Classification, focusing on data protection and governance, and legal requirements for AI deployment.

This structural distinction was introduced to enhance clarity and usability, allowing researchers to better distinguish between ethical reflection and legal obligations, while maintaining their interconnection.

Subsequently, the revised template (v2) was presented to the Ethics and Legal Advisory Board (ELAB) of EYE-TEACH project during an online meeting held on 2 March 2026. The ELAB provided additional expert feedback, particularly regarding the section on the ethics of artificial intelligence and the alignment with emerging regulatory frameworks. Based on this input, a set of minor revisions was implemented, leading to the final version of the template (v2.1) that is the version currently adopted within the project.

Workflow for Template Completion and Review

A structured workflow was established to support the consistent and effective use of the Research Protocol Template across all experimental activities within the project. For each study involving human participants and contributing to the development of the AI-assisted eye-tracking analytics tool for educational use, the following process was implemented:

— Initial draft submission: each Principal Investigator prepared and submitted a first draft of the completed template to the CNR ethics team in Word format.

— Review and support: the CNR team reviewed the submitted draft and provided detailed feedback, focusing on ethical consistency and completeness adequacy of risk assessment and mitigation strategies, compliance with data protection requirements, clarity and transparency of information provided. This review process was carried out through email exchanges and dedicated online meetings, allowing for direct interaction with the researchers and iterative refinement of the template.

— Revision and Finalisation: based on the feedback received, the scientific responsible revised the template accordingly.

— Final Submission: the final version of the completed template was submitted by the scientific responsible in PDF format, dated and signed, accompanied by all relevant supporting documentation, as suggested in the Attachments Checklist

(e.g., informed consent forms, information sheets, ethics approvals, DPIA summaries where applicable).

This workflow facilitated both consistency across studies and context-sensitive adaptation, while promoting ongoing dialogue between ethical experts and researchers.

Part I: Structure and Rationale of the EYE-TEACH Research Protocol Template

This part presents the structure and underlying rationale of the EYE-TEACH Research Protocol Template, developed as an internal harmonisation tool to support ethical reflection and facilitate consistency in addressing ethical and legal requirements across all project activities. The template is designed to guide researchers in systematically identifying, analysing, and mitigating ethical, integrity and data protection issues arising in studies involving human participants and AI technologies.

At the same time, it is important to clarify its scope and limitations: the template is not meant to replace formal ethics approvals required by institutional review boards or national ethics committees, nor does it substitute legally mandated documentation such as those required under applicable data protection regulations. Rather, it complements these processes by facilitating their preparation and enhancing transparency within the consortium.

The following sections provide a detailed description and justification of all the questions included in the template, organised into its two main parts: Section A, dedicated to research ethics and the ethics of artificial intelligence, and Section B, focused on data protection and AI risk classification.

Section A: Research Ethics and Ethics of Artificial Intelligence

Section A of the Research Protocol Template is grounded in the fundamental ethical principles established by key international, European, and national frameworks for the protection of human research participants, with particular attention to children. These include, at the international level, the *UN Convention on the Rights of the Child* (1989),

and, at the European level, the *Ethics in Social Sciences and Humanities guidelines* (2021), as well as, at the national level, the CNR Research Ethics and Integrity Committee's *Child Protection Policy and Code of Conduct* (2016). In line with these documents, the template has been designed to systematically capture essential ethical criteria for research involving minors, including: (i) the need to balance potential benefits against any burdens imposed on children; (ii) the requirement to limit their participation to scientifically sound and socially valuable studies; (iii) the implementation of robust risk assessment and management procedures; and (iv) the adoption of a dual consent process, combining the child's informed assent with the consent of parents or legal guardians.

In addition, a dedicated subsection **A7 Ethics of Artificial Intelligence** is aimed at assessing how each study contributes to the responsible development of the AI-assisted eye-tracking analytics tool. This subsection is informed by key European and international guidelines on AI and data use, particularly in educational contexts, such as the *Ethics Guidelines for Trustworthy Artificial Intelligence* (2019), the *UNICEF Policy Guidance on AI for Children* (2020), and the *Ethical Guidelines on the Use of AI and Data in Teaching and Learning for Educators* (2022). These ethical frameworks emphasise requirements such as fairness, transparency, accountability, human oversight, and the protection of children's rights in the design and use of AI systems.

The rationale and objectives of each subsection included in Section A are described in detail below.

A1 Study Identification

Subsection **A1 Study Identification** is designed to make clear the responsibility, institutional context, and key characteristics of each experimental study conducted within the EYE-TEACH consortium. This information is essential to guarantee transparency and accountability across all research activities. Question **1.1 Study Title** requires the full title of the study, indicating whether it is provisional or final, to uniquely identify the research activity and track its development over time. Question **A1.2 EYE-TEACH Task(s) / Work Package(s)** situates the study within the project structure by specifying the relevant tasks and work packages, and any cross-links with other activities, thereby supporting coordination and alignment within the consortium. Question **A1.3 Principal Investigator (PI)** collects the contact details and institutional affiliation of the person with primary scientific and ethical responsibility for the study,

providing a clear point of accountability. Question **A1.4 Co-Investigators** extends this mapping by requiring the identification of all researchers involved, including their roles and contributions, thus clarifying responsibilities within the research team. Question **A1.5 Consortium Partner Institutions** captures the multi-partner dimension of the project by listing all participating institutions, their legal status, and the responsible PI at each site, which is particularly important for governance and compliance in collaborative research. Question **A1.6 Expected Duration** requires the indication of the study timeline (start and end dates), enabling monitoring of research activities and their alignment with project milestones, as well as with the ethical approvals issued by the partners' ethics committees. Finally, Question **A1.7 Funding Source(s)** aims to provide transparency regarding financial support, by specifying whether additional funding sources beyond the EYE-TEACH European grant are involved, which may have implications for ethical oversight and reporting obligations. Together, these questions provide a comprehensive overview of each study's identity, governance, and organisational context.

A2 Scientific Background and Rationale

Subsection **A2 Scientific Background and Rationale** is intended to make explicit that each experimental study conducted within the EYE-TEACH project is grounded in sound scientific principles, methodological rigor, and clear relevance to the overall project objectives. Question **A2.1 Abstract** requires a concise summary of the study, including its objectives, methods, and expected outcomes, providing an accessible overview that facilitates both ethical review and internal understanding. Question **A2.2 Scientific Background** asks researchers to describe the theoretical framework and relevant literature, including the specific knowledge gap the study aims to fill, thus demonstrating the study's scientific justification and its place within existing research. Question **A2.3 Research Questions / Hypotheses** focuses on the articulation of the core research questions or hypotheses, facilitating the clarity about the purpose and design of the study. Question **A2.4 Expected Scientific Contribution** requires an explanation of the new knowledge the study is expected to generate and how it contributes to the broader goals of the EYE-TEACH project, particularly in advancing the development and validation of the AI-assisted eye-tracking analytics tool for educational purposes. Finally, Question **A2.5 Study Pre-registration** addresses research transparency and integrity by asking whether the study has been pre-

registered and on which platform, promoting good scientific practices such as reproducibility and accountability.

A3 Study Design and Methodology

Subsection **A3 Study Design and Methodology** is aimed at assessing both the scientific validity and the ethical implications of the experimental procedures adopted in each study. Question **A3.1 Study Design** requires a clear description of the overall methodological approach (e.g., experimental, quasi-experimental, correlational, longitudinal, cross-sectional, or mixed-methods), allowing for an evaluation of whether the chosen design is appropriate to address the stated research questions. Question **A3.2 Variables** asks researchers to identify independent, dependent, and control variables, as well as to describe how experimental control is ensured, which is essential for assessing the internal validity and robustness of the study. Question **A3.3 Procedures** focuses on the participant experience, requiring a detailed, step-by-step account of all stages, from recruitment to debriefing, including the estimated time commitment, which is crucial information for assessing potential burdens and risks for participants. Question **A3.4 Materials and Instruments** requires a comprehensive list of all tools used in the study (e.g., questionnaires, tasks, stimuli, software, and equipment), including references to validated instruments where applicable, to assess both scientific reliability and potential risks associated with their use. Question **A3.5 Setting(s)** asks to specify the context in which the study takes place (e.g., laboratory, online environment, classroom, or multiple sites) to identify the relevant ethical considerations accordingly. Question **A3.6 Randomization / Counterbalancing**, where applicable, requires a description of randomization procedures and counterbalancing strategies, which are essential to ensure internal validity and to minimise selection bias among participants. Finally, question **A3.7 Statistical Analysis Plan** asks for a brief outline of the planned analyses, supporting transparency and methodological rigor. All these questions are intended to assess that the study design is not only scientifically valid, but also ethically appropriate in terms of a fair distribution of conditions, burdens and risks for participants.

A4 Study Participants

Subsection **A4 Study Participants** collects detailed information on participant characteristics, recruitment, and rights protection, to evaluate that their involvement in each study is ethically justified and appropriately safeguarded. Question **A4.1 Target**

Population requires a clear description of the specific individuals or groups involved, including the characteristics that make them relevant to the research objectives. Question **A4.2 Sample Size and Justification** asks researchers to indicate the planned sample size and provide a justification, such as a power analysis or methodological rationale, to estimate that the number of participants is adequate to achieve scientific validity while avoiding unnecessary involvement. Questions **A4.3 Inclusion Criteria** and **A4.4 Exclusion Criteria** require a transparent definition of the conditions for participation, which is essential to ensure fairness, consistency, and the protection of individuals who may be most at risk. Question **A4.5 Recruitment Strategy** focuses on how participants are identified and approached, allowing for the assessment of whether recruitment methods are appropriate, non-coercive, and respectful of participant autonomy. Question **A4.6 Voluntary Participation** requires clarification on whether participants are volunteers and whether any form of compensation is provided; in such cases, researchers must describe and justify the type and amount of incentives, so that they do not constitute undue inducement to participate in the study. Question **A4.7 Children/Minors** specifically addresses the involvement of minors, requesting information on age range, justification for their inclusion, and recruitment procedures, in line with the need greater ethical safeguards for children. Finally, question **A4.8 Participant Well-Being** requires a comprehensive description of the measures implemented to protect participants before, during, and after the study, including strategies to prevent discomfort, coercion, or harm, particularly for children, so that the rights, dignity, and well-being of participants are protected throughout the research process.

A5 Risk-Benefit Assessment

Subsection **A5 Risk–Benefit Assessment** is designed to assess the potential risks and expected benefits associated with each study, in line with the ethical principle of proportionality. Question **A5.1 Potential Risks** requires researchers to identify all foreseeable risks to participants, categorised into: (i) physical risks, such as discomfort, fatigue, health effects from equipment, (ii) psychological risks, such as stress, anxiety, emotional distress, (iii) social risks, such as stigmatization, damage to reputation, (iv) economic risks, such as costs, loss of employment opportunities, (v) privacy risks, such as unauthorized access, re-identification, unintended disclosure, (vi) discrimination risks, such as unfair treatment based on inferred characteristics, and (vii) any other study-specific risks. For each identified risk, researchers must

assess both its severity (low, medium, high) and likelihood (unlikely, possible, likely), enabling a structured and transparent evaluation of potential harm. Question **A5.2 Risk Mitigation** asks for a detailed description of the measures implemented to minimise the above-mentioned risks, such as procedural safeguards, technical protections, or participant support mechanisms. Question **A5.3 Potential Benefits** requires an articulation of both the direct benefits for participants (if any) and the broader scientific and societal benefits, including contributions to knowledge and the development of the AI-assisted eye-tracking tool. Question **A5.4 Risk-Benefit Ratio** then asks researchers to justify why the anticipated benefits outweigh the identified risks, so that participation is ethically acceptable and proportionate. Finally, question **A5.5 Incidental Findings** addresses the management of unexpected findings that may arise during the study, requiring researchers to define policies for their identification, communication, and handling.

A6 Informed Consent and Ethics

Subsection **A6 Informed Consent and Ethics** is dedicated to assessing that participation in each study is based on free, informed, and voluntary consent, thereby safeguarding participants' autonomy and fundamental rights. The questions are intended to help researches appreciate that informed consent should not be considered as a mere formal requirement, but as an ongoing ethical process that respects participants' understanding, voluntariness, and rights throughout the study. Question **A6.1 Adult Consent Process** requires a detailed description of how informed consent is obtained (e.g., written signature or online confirmation), as well as a clear account of all information provided to participants prior to consent; in the case of a study involving minors, this question requires specification of procedures for obtaining parental or legal guardian consent. Question **A6.2 Child/Minor Assent Process** focuses on the active involvement of children in the decision-making process, requiring researchers to explain how the minor's willingness to participate is respected and how assent is obtained in an age-appropriate manner, including the information provided to them. Question **A6.3 Comprehension Check** asks researchers to describe any strategy (such as simplified language, visual aids, or interactive explanations) adopted to ensure that participants, and especially children, fully understand what they are consenting to. Question **A6.4 Right to Withdraw** requires a clear explanation of how participants are informed of their right to withdraw from the study at any time, without any consequences. Question **A6.5 Languages** aims to

promote accessibility and inclusivity by requiring the indication of the language(s) in which consent materials are provided, in line with good practice of providing informed consent materials in participant's native language. Finally, question **A6.6 Documentation** asks researchers to specify the status developed, distributed, or signed) of information sheet(s) and consent form(s) and to attach them, where available, to the completed and signed template.

A7 Ethics of Artificial Intelligence

Subsection **A7 Ethics of Artificial Intelligence** is designed to assess how each study contributes to the responsible development and use of the AI-assisted eye-tracking analytics tool, with a focus on key ethical requirements such as fairness, transparency, human oversight, accountability, and societal impact, so that the development of the AI system within the project is aligned with a human-centred and ethically grounded approach. Question **A7.1 Contribution to AI Development and Use** asks researchers to explain how the involvement of human participants in each study supports the design, development, or improvement of the AI system, for example through data collection, co-design activities, or testing in educational settings. Question **A7.2 Transparency and Explainability** requires a clear description of the information provided to participants about the use of AI within the study, including how AI models or tools function and how participants' data contribute to their development, thereby promoting informed participation. Question **A7.3 Fairness and Non-discrimination** focuses on the identification and mitigation of potential biases, asking researchers to describe strategies to prevent discriminatory outcomes related to algorithmic processes or data characteristics, including those linked to cognitive, physiological, cultural, or technological factors. Question **A7.4 Human Agency and Oversight** addresses the role of human control, requiring an explanation of how AI-driven decisions may affect participants and future users, and whether mechanisms are in place to ensure meaningful human oversight of such decisions. Question **A7.5 Safety and Accountability** asks researchers to describe how the study contribute the reliability, robustness, and safe functioning of the AI system, as well as clarify responsibilities in its development and use. Finally, question **A7.6 Social Impact** broadens the perspective to the educational context, requiring an assessment of how the AI system may influence teaching and learning processes, including potential benefits such as the development of new digital skills, as well as risks such as deskilling or unintended negative impacts on teachers and students.

A8 Research Ethics and Integrity

Subsection **A8 Research Ethics and Integrity** is intended to assess the extent to which each study complies with established research integrity standards and to identify any additional ethical issues that may arise during the research. Question **A8.1 Ethical Clearance** requires researchers to indicate whether ethical approval has been obtained, submitted, or is under development with the relevant institutional ethics committee. If approval has been granted, details must be provided and supporting documentation attached, along with information on any subsequent changes requiring notification to the committee; whereas in cases where approval is not required, a clear justification must be given. Question **A8.2 Ethics Mentor(s)** asks whether the study has one or more professionals responsible for providing ethical guidance in the study and seeking ethical clearance, including their institutional affiliations and contact information, thus strengthening ethical oversight. Question **A8.3 Conflicts of Interest** requires the declaration of any potential conflicts involving researchers or stakeholders (e.g., institutions, companies, teachers, students), promoting transparency and impartiality. Question 8.4 Results Dissemination focuses on how study findings will be communicated, including whether and how results will be shared with participants, in order to promote accountability and respect for participants' contribution. Question **A8.5 Publication Plans** addresses the intended publication strategy, including commitments to open access, in line with principles of transparency, reproducibility and accessibility of publicly funded research. Question **A8.6 Potential Misuse** requires an assessment of risks related to the inappropriate use of data or results and the identification of safeguards to prevent such misuse. Question **A8.7 Dual-use Concerns** further expands this analysis by asking whether the research outcomes or technologies could be repurposed for harmful or unintended applications, including military uses, and what mitigation strategies are in place. Finally, question **A8.8 Other Ethical Issues** provides space to identify any additional ethical considerations not covered elsewhere, such as cultural, social, or political sensitivities.

Section B: Data Protection and AI Risk Classification

Section B of the Research Protocol Template addresses the legal and regulatory dimensions of research involving human participants, with a particular focus on data protection and the use of artificial intelligence. It is grounded in the key principles of

the General Data Protection Regulation (GDPR), which are especially relevant in research contexts, including lawfulness, fairness and transparency, purpose limitation, data minimisation, accuracy, storage limitation, integrity and confidentiality, and accountability. In addition, given that the EYE-TEACH project is currently in the design phase of an AI-assisted tool intended for future deployment, particular relevance is attributed to the principle of Data Protection by Design and by Default, as established in Article 25 GDPR. This principle requires that data protection considerations be integrated into the design and architecture of the system from the outset, rather than addressed retrospectively, and that, by default, only personal data strictly necessary for each specific purpose of processing are collected, processed, and retained. The operationalisation of this principle within the project is reflected in the ethics and privacy by design approach described in the Methodology section of the present deliverable. These principles should guide the collection, processing, and management of personal data within the EYE-TEACH project, so that the rights and freedoms of participants are effectively protected.

In this context, a fundamental requirement of the GDPR is the clear identification of the roles and responsibilities of all parties involved in data processing activities. The principle of accountability, as set out in Article 5(2) of the GDPR, stipulates that the data controller —the entity that determines the purposes and means of processing— must be clearly identified for each study. In collaborative research settings such as EYE-TEACH, where multiple institutions are involved in data collection and processing, it is important to establish whether a joint controllership arrangement is in place. If so, a formal agreement must be made in accordance with Article 26 GDPR, defining the respective responsibilities of each controller with regard to data subjects. Similarly, where third parties process personal data on behalf of the controller, their role as data processors must be formalised through data processing agreements in accordance with Article 28 of the GDPR. The data controller bears primary responsibility for assessing and implementing appropriate technical and organisational measures to ensure processing security, managing communication with data subjects regarding the exercise of their rights and determining whether processing activities require a Data Protection Impact Assessment (DPIA) under Article 35 GDPR. A DPIA is mandatory where processing is likely to result in a high risk to individuals' rights and freedoms. This includes the large-scale processing of sensitive or biometric data; the systematic monitoring of participants; the involvement of vulnerable subjects, such as children; or the deployment of innovative

technologies, such as AI systems. Furthermore, this section reflects the emerging regulatory framework established by the AI Act, which, like the GDPR, takes a risk-based approach to the development and use of AI systems. The template helps researchers to assess whether their activities qualify for research exemptions or may be subject to future regulatory obligations, especially if the systems are intended to be tested in real world condition and developed for market release.

To operationalise these requirements, Section B is structured into three complementary subsections: **B1 Data Protection and Management**, which collects detailed information on the types of data processed, roles and responsibilities, and technical and organisational safeguards; **B2 Informed Consent and Data Subject Rights**, which focuses on the legal basis for data processing and the mechanisms through which participants can exercise their rights; and **B3 Artificial Intelligence**, which addresses the use of AI within each study, including its purpose, contribution to system development, and its classification under the AI Act. It should be noted that Section A is not only relevant to research ethics and ethics of AI, but also serves a functional purpose with respect to Section B. The information gathered in Section A, particularly regarding study design, participant characteristics, data collection procedures, and the use of AI, provides essential context for understanding the scope and nature of the processing activities, thereby enabling a more accurate and complete assessment of the applicable data protection requirements. In this sense, the two sections are complementary and should be read in conjunction. The rationale and objectives of each subsection included in Section B are described in detail below.

B1 Data Protection and Management

Subsection **B1 Data Protection and Management** is intended to collect information on the nature of the data processed, the allocation of responsibilities, and the safeguards implemented to assess compliance with data protection requirements, under the GDPR. Overall, this subsection allows to verify that data processing activities are clearly defined, responsibly managed, and adequately safeguarded, in line with applicable legal standards. Question **B1.1 Data Status** requires researchers to clarify whether the study involves data relating to natural persons, distinguishing between: (i) personal data, (ii) data that are anonymous at source, (iii) data that will be anonymised during the study, or (iv) cases where no such data are involved. If data are considered anonymous at source, researchers must explain why re-identification is not possible; while if anonymisation is planned, they must describe the process,

recognising that anonymisation itself constitutes a data processing operation. If no personal data are involved, researchers are instructed to proceed directly to Section B3. Question **B1.2 Types of Data Collected** requires a detailed specification of all categories of data collected, including: (i) demographic, (ii) behavioural, (iii) physiological/biometric, such as eye-tracking data, (iv) audio, (v) video, (vi) self-reported data, or (vii) other types, thus enabling an assessment of the sensitivity and scope of data processing activities.

The subsection then addresses roles and responsibilities. Question **B1.3 Data Controller(s)** asks researchers to identify the entity or entities responsible for determining the purposes and means of processing personal data, and, in cases of joint controllership, to indicate whether appropriate agreements are in place to define respective responsibilities toward data subjects. Question **B1.4 Data Processor(s)** focuses on third parties that may process data on behalf of the controller (e.g., technology providers or software developers), requiring clarification of their role and the existence of formal data processing agreements. Finally, the subsection examines data protection safeguards. Question **B1.5 Security Measures** requires researchers to indicate and briefly describe the technical and organisational measures implemented to ensure data security both at rest and in transit, such as encryption at rest or in transit, pseudonymisation, access control mechanisms, secure storage solutions, logging systems, and staff training. Question **B1.6 Data Protection Impact Assessment** (DPIA) addresses the need for a DPIA in cases where processing may pose high risks to individuals' rights and freedoms. Researchers should assess whether the study involves elements such as (i) profiling, (ii) large-scale processing of sensitive data, including biometric data, (iii) systematic monitoring, (iv) processing of data of vulnerable subjects (e.g., children), or (v) the use of new technologies. Based on this assessment, they must indicate whether a DPIA is required and provide a justification for their decision.

B2 Informed Consent and Data Subject Rights

Subsection **B2 Informed Consent and Data Subject Rights** is intended to assess that the processing of personal data in each study is grounded on a valid legal basis and that participants can effectively exercise their rights, in compliance with the GDPR. Overall, this subsection allows to evaluate that data processing is conducted in a manner that is lawful, transparent, and respectful of participants' control over their personal data. The legal basis for data processing is the explicit consent of

participants, which complements the ethical consent to participate in research (see Subsection A6 Informed Consent and Ethics). As clarified by the European Data Protection Board in paragraph 15 of Opinion 3/2019 on the interplay between the Clinical Trials Regulation and the GDPR (adopted pursuant to Article 70(1)(b) GDPR), the two consents serve different purposes, are subject to different conditions, and must therefore be sought and documented separately. This implies that participants must be clearly informed about how their data are collected, used, and protected; must explicitly agree to such processing; and must be able to withdraw their consent at any time. Question **B2.1 Consent for Data Processing** therefore examines how consent is obtained, requiring clarification on (i) whether consent for data processing is collected separately from or together with participation consent, (ii) how it is properly documented (e.g., signature or digital confirmation), and (iii) whether the information is provided in a concise, transparent, and accessible manner, using clear language appropriate to the target population, especially in the case of children. Question **B2.2 Right to Withdraw Consent and Data Erasure** focuses on participants' ability to withdraw their consent for data processing, distinguishing this from withdrawal from the study itself. Researchers must explain how withdrawal can be requested and whether it is automatic or requires a separate action. As a general rule, withdrawal of consent should lead to the erasure of the participant's data (Art. 17.1.b, GDPR). However, where erasure is considered not feasible, specifically because it would seriously impair the achievement of the research objectives or undermine the integrity of the results, researchers are required to provide a clear and explicit justification for retaining the data notwithstanding the withdrawal of consent (Art. 17.3, GDPR). Finally, question **B2.3 Other Data Subject Rights** requires researchers to describe how participants can exercise their rights under data protection law, including the right of access, rectification, erasure, and restriction of processing, as well as to identify a clear contact point for handling such requests.

B3 Artificial Intelligence

Subsection **B3 Artificial Intelligence** focuses on the use of AI within each study, its interaction with participant data, and its regulatory implications, including the applicability of the EU AI Act and, where applicable, the classification of the AI application within the specific risk class defined by the regulation. It should be noted that not all questions in this subsection are applicable to every study. Some of them are only relevant where the study directly involves the use or development of an AI

system. Indeed, certain studies within the EYE-TEACH project may be purely preparatory in nature, such as those aimed at assessing user acceptance, gathering design requirements, or collecting data intended for future AI model training, and may therefore not yet entail the deployment or development of an AI system as such. In these cases, researchers are invited to answer only those questions that are pertinent to their specific study, clearly indicating where a question is not applicable and briefly explaining the reason. Question **B3.1 Purpose and Type of AI Used** requires researchers to describe the specific purposes for which AI tools are employed (such as eye-tracking analysis, behavioural modelling, or data classification), and to specify the types of models, algorithms, or platforms used (e.g., commercial, open-source, or custom-developed). Question **B3.2 Contribution to AI Development and Data Used** examines whether and how the study contributes to the development of the AI-assisted ET-analytics system, requiring clarification on the role of the study in the design or improvement of the system and on how collected data are used (e.g., for training, validation, or testing of AI models or system).

Question **B3.3 AI Act Applicability** asks researchers to determine whether the AI system falls under research exemptions (e.g., developed solely for scientific purposes, Art. 2(6) AI Act) or is intended for future market or operational use (Art. 2(8) AI Act), which has implications for regulatory compliance. In the latter case, which is clearly relevant for the AI-assisted eye-tracking analytics tool being developed within the EYE-TEACH project, the way experimentation is conducted becomes a decisive factor in determining the applicability of the regulation. Specifically, when an AI system intended for deployment is tested in conditions that qualify as "real-world conditions" (Art. 3.57 AI Act), the AI Act applies and the related obligations, including those incumbent upon deployers, must be complied with. Question **B3.4 Testing Environment** therefore requires a description of the context in which AI systems are tested (e.g., laboratory or real classroom settings) and an assessment of whether such environments qualify as "real-world conditions" within the meaning of the AI Act, as this determination is directly relevant to establishing which regulatory obligations apply. Finally, the subsection focuses on AI risk classification.

Where the AI Act is determined to be applicable, a further critical step is the correct classification of the AI system within the risk categories established by the regulation, as this classification determines the specific obligations that must be fulfilled. Questions 3.5 and 3.6 are designed to support this assessment by gathering the information necessary to evaluate the nature, scope, and potential impact of the AI

system's functions. Question **B3.5 Inferences and Derived Data** requires researchers to identify the types of inferences generated by the AI system (e.g., cognitive, emotional, or learning-related) and to assess whether these could reveal sensitive information not explicitly collected, raising potential data protection concerns. In this regard, a matter of particular regulatory significance is whether the AI system generates inferences relating to the emotional states of individuals. Under Article 5(1)(f) of the AI Act, AI systems that infer the emotions of natural persons in educational institutions are classified as presenting an unacceptable risk and are therefore prohibited, except where used for medical or safety reasons. Given that the AI-assisted eye-tracking analytics tool developed within EYE-TEACH is intended for eventual market deployment, this prohibition applies regardless of the conditions under which individual experimental studies are conducted. It is therefore of critical importance that, already at this design stage, the system architecture incorporates appropriate safeguards to ensure that emotion inference does not constitute a function of the system, and that this design choice is clearly documented.

Question **B3.6 Scope of AI Function** asks researchers to evaluate whether the AI system may pose risks to individuals' health, safety, or fundamental rights, or influence decision-making processes, and to clarify the functional role of the AI (e.g., supporting, enhancing, or partially replacing human assessment), including whether appropriate human oversight is maintained. In the absence of emotion inference, the system would in principle fall within the high-risk category established by Annex III, paragraph 3(b) of the AI Act, which covers AI systems intended to evaluate learning outcomes in educational settings. However, the same application may be subject to a more moderate risk classification if the conditions set out in Article 6(3) of the AI Act are met, namely where the system does not pose a significant risk of harm to health, safety, or fundamental rights and does not materially influence individual decision-making. This may be the case where the conditions set out in Article 6(3) are met, in which circumstance the system may be classified as presenting a moderate rather than high risk. A necessary condition for this more favourable classification is that the processing does not involve the profiling of individual participants. In this respect, it is worth noting that the specific objective of the EYE-TEACH project (namely the assessment of learning outcomes through eye-tracking data) does not, in itself, constitute profiling within the meaning of the regulation, insofar as it is directed at evaluating reading comprehension performance rather than at building comprehensive profiles of individual users. However, this distinction must be actively

preserved throughout the subsequent phases of the project. It will therefore be essential to ensure that individual assessments remain discrete and temporally bounded, and that the system is designed in such a way as to prevent the accumulation of individual evaluation results over time into longitudinal profiles of students. This requirement should be explicitly addressed in the technical design of the system and verified at each stage of development and deployment. A formal assessment of these aspects will be carried out within the Data Protection Impact Assessment (DPIA) planned for the subsequent phases of the project, specifically in relation to the processing activities involving personal data collected through the AI-assisted eye-tracking tool once developed and operationalised. The DPIA will provide a structured and documented evaluation of the risks associated with those processing activities and of the adequacy of the technical and organisational measures adopted to mitigate them.

Part II: Ethical and Legal Considerations Emerging from the Completed Templates by the Principal Investigators of Experimental Studies Involving Human Participants

This section provides a structured overview and assessment of the ethical and legal dimensions emerging from the Research Protocol Templates completed by the Principal Investigators of the experimental studies conducted within the EYE-TEACH project. The primary objective is to support partners in reflecting on the ethical and legal implications of their study designs, while also ensuring ongoing monitoring of the project's overall ethical and regulatory sustainability. The section is organised as follows.

First, it presents a concise overview of the key characteristics of the four completed templates, including the relevant Work Packages and Tasks, study titles, partner institutions involved, participant samples, methodological approaches, and procedural features. This overview is intended to provide a clear and comparable snapshot of the experimental activities across the project. Second, the section offers

a targeted ethical and legal assessment for each study, focusing on the most relevant aspects emerging from both Section A (Research Ethics and Ethics of Artificial Intelligence), and Section B (Data Protection and AI Risk Classification) of the template. The aim of this assessment is not to replicate formal ethics review processes, but rather to identify potential issues early, provide constructive recommendations, and facilitate alignment with applicable ethical standards and legal requirements, including data protection obligations. Finally, building on the individual analyses, the section concludes with the identification of cross-cutting ethical, legal, and data protection issues that emerge across the studies. These are discussed in light of key European ethical guidelines and regulatory frameworks, with the purpose of supporting a coherent and harmonised approach to ethical and legal compliance throughout the project.

Overview of EYE-TEACH Experimental Studies

This section provides a concise overview of the experimental studies conducted within the EYE-TEACH project, as documented in the completed Research Protocol Templates. In particular, the following four templates have been submitted:

- Vignettes study (WP1, T1.2): University of Antwerp & Open Universiteit; ~300 in-service teachers/educators read and evaluate up to four AI-system scenarios and answer questions. Aim: assess teacher preparedness and acceptance for AI and inform teacher-centred hybrid-intelligent systems.
- Dashboard co-design study (WP1, T1.3 Phases 1-2): Open Universiteit, University of Antwerp, Copernicus Science Center; ~18-20 in-service teachers. Activities: prototype visualization presentations, individual and focus-group think-aloud, collaborative design tasks. Aim: elicit design considerations, usability feedback, and insights into teachers' visual/cognitive engagement.
- Dashboard user study (WP1, T1.3 Phase 3): University of Antwerp & Open Universiteit; in-service teachers (N to be decided). Procedure: information-retrieval tasks on a dashboard with eye-tracking and between-task questionnaires; Aim: inform design/development of the AI-assisted ET-analytics teacher dashboard.
- Eye-movement metrics validation (WP2, T2.3): University of Valencia & University of Turku; ~50-100 children aged 10-13. Procedure: reading two on-

screen texts with eye-tracking, comprehension questions, and cognitive-skill assessments. Aim: validate predictive relationships between eye-movement measures and reading comprehension and inform the AI model.

Methodologically, the approach proposed in the project, demonstrates breadth and complementarity by combining a large-scale vignette evaluation with small-scale participatory co-design, experimental user testing with eye-tracking, and validation work with children, thereby enabling both broader inference and deep, actionable design insight. The sequence from vignettes and co-design to an eye-tracked prototype study reflects an iterative, user-centred workflow that supports ecological validity: attitudes and requirements are gathered, translated into prototypes, and then tested for interaction and cognitive response. **Table 1** summarises the main characteristics of each study, including their scope, partners involved, target populations, procedures, and expected contributions. Together, these studies illustrate a coherent and complementary mixed-methods approach, combining large-scale surveys, participatory design, experimental testing, and validation work to support the development of the AI-assisted eye-tracking analytics tool.

Table 1. Summary of the characteristics of the studies reported in the Research Protocol Template.

WP/Task	Study title	Partners involved	Sample	Procedure	Main contribution
WP1, T1.2	Vignettes study on AI system design elements and teachers' preparedness and acceptance (Vignette Study)	University of Antwerp, Open Universiteit	In-service teachers and educators (~300)	Participants read and evaluate up to four system scenario and answer to specific questions	Evaluate the readiness of teachers' preparedness for AI in education and acquire evidence to support teacher-centred hybrid-intelligent systems
WP1, T1.3, Phase 1 and 2	Co-design of an AI-Assisted ET-analytics teacher dashboard	Open Universiteit, University of Antwerp, Copernicus	In-service teachers and educators (~18-20)	Participants take part in co-design workshops to evaluate	Get design considerations and features which will guide the development of

	(Dashboard Co-design Study)	Science Center		prototype visualizations. Activities include individual (Phase 1) and focus-groups (Phase 2) think-aloud and collaborative design tasks to gather feedback on usability, interpretation, and desired features	the prototype and insights on how teachers visually and cognitively engage with the prototype
WP1, T1.3, Phase 3	Teacher's use of an AI-Assisted ET-analytics teacher dashboard: A user study (Dashboard User Study)	University of Antwerp, Open Universiteit	In-service teachers and educators (number to be decided)	Participants complete dashboard information-retrieval tasks while being eye-tracked and answer questions about the retrieved information and their experience (e.g., cognitive load)	Acquire insights about the design and development of the teacher dashboard prototype
WP2, T2.3	Eye movement metrics validation study	University of Valencia, University of Turku	Children aged 10-13 years old (~50-100)	Participants read two texts on the monitor while eye-tracking is recorded.	Obtain information about the predictive relationship between eye-movement measures and reading

					comprehension outcomes as well as inform the AI model

Ethical and Legal Assessment of Completed Templates

Below is an analysis of the most relevant responses, from both an ethical and legal perspective, included in Section A and B of each of the four Research Protocol Templates compiled by EYE-TEACH partners responsible for studies involving human participants, identifying areas where further clarification or improvement would be beneficial.

Analysis of the completion of Section A for the Vignette Study (WP1, T1.2)

The "Vignette Study" is an online survey targeting in-service teachers and educators across multiple European countries, designed to investigate their preparedness for and acceptance of AI-supported educational technologies. As such, it constitutes a low-risk study involving adult professionals, with no direct use of AI tools and no involvement of vulnerable populations. The completed template reflects an overall appropriate ethical framing, and formal ethical clearance has already been obtained from the *Ethics Committee for Social Sciences and Humanities* of the University of Antwerp, as indicated in **A8.1 Ethical Clearance**.

Based on the information provided in the submitted template, the following aspects merit ethical considerations.

A first aspect concerns the use of a participation incentive in the Spanish context, as reported in response to question **A4.6 Voluntary Participation and Incentives**, where participants could enter a prize draw organised by the EYE-TEACH partner Intralíneas, whereas in all other national contexts no compensation is provided. From an ethical perspective, the central issue is whether such an incentive could constitute undue inducement, thus compromising the voluntariness of consent. In this case, the incentive can reasonably be considered ethically acceptable: it is limited and indirect, as it does not guarantee a reward and requires an additional voluntary step by participants, and is offered in the context of a study posing minimal risks to adult

professionals. These features, taken together, make it unlikely that the incentive constitute undue inducement or compromise the voluntariness of consent, especially given its low monetary value and optional nature.

A second aspect concerns the identification of potential risks in response to question **A5.1 Potential Risks**, where only mild physical fatigue is identified, classified as low in severity and possible in likelihood. This assessment is broadly consistent with the nature of an online survey involving adult professionals. However, even in anonymised surveys, privacy risks should at least be considered, especially given the presence of open-text responses where participants might inadvertently disclose sensitive information. The research team acknowledges, in response to **A5.5 Incidental Findings**, the residual possibility of unintended re-identification. While this does not constitute a substantive ethical concern given the low-risk nature of the study, one possible strategy to further align the protocol with the privacy by design approach adopted by the project would be to briefly outline in advance how any inadvertent disclosure of sensitive information through open-text responses would be handled by the research team (e.g., whether such data would be deleted or otherwise managed to minimise this risk). This is offered as a general suggestion rather than as a recommendation requiring action, given the ethical clearance already obtained.

Finally, with respect to subsection **A7 Ethics of Artificial Intelligence**, it is worth noting positively that the study explicitly positions itself as a foundational input to the human-centred design of the AI-assisted eye-tracking analytics tool, gathering teachers' perceptions and expectations to inform system development, as indicated in **A7.1 Contribution to AI Development and Use**. This approach is well aligned with the ethical principles guiding the project. It is worth noting that, in **A7.2 Transparency and Explainability**, the brief answer refers to the transparency of the research aim, which can be found also in EYE-TEACH project webpage. While this is a positive element, to meet the requirement of transparency and explainability in the context of AI ethics, participant could be provided with more detailed and study-specific information about the role of AI in the project, the functioning and implications of AI system, and how their data may contribute to AI system development.

Analysis of the completion of Section B for the Vignette Study (WP1, T1.2)

With respect to Section B, the "Vignette Study" presents a specific and noteworthy profile from a data protection perspective. The study is designed as an anonymous survey, and the research team confirmed that no directly identifying information is collected. Consequently, the research team considers the GDPR not applicable to this study. However, this assessment warrants further scrutiny. As declared in response to question **B1.2 Types of Data Collected** the survey collects a combination of demographic and professional attributes, including the country in which the teacher works, gender, school level, age range of students taught, subject taught, level of education, years of teaching experience, and professional role. While none of these variables constitutes a direct identifier, their combination could, in principle, allow for the re-identification of individual respondents through cross-referencing with publicly available information, particularly in contexts where the pool of potential participants is limited or well-defined.

That said, a proportionate assessment of this risk leads to a reasonably favourable conclusion. The survey was administered across multiple European countries through the networks of the project partners, resulting in a broad and heterogeneous participant pool that significantly reduces the practical likelihood of re-identification. Furthermore, the data collected consist exclusively of professional opinions and perceptions regarding AI-supported educational technologies, and do not include special categories of data within the meaning of Article 9 of the GDPR. The potential harm associated with any hypothetical re-identification is therefore limited. On this basis, while a strictly formal application of the GDPR definition of personal data, which includes any information relating to an identifiable natural person, however indirect the means of identification, might suggest that some degree of caution is warranted, the position adopted by the research team can be considered acceptable in light of the low re-identification risk and the non-sensitive nature of the data involved. It is nonetheless recommended that this assessment be explicitly documented in the study records, so as to demonstrate that the question of anonymity was actively considered and evaluated rather than merely assumed.

Regarding the remaining inconsistencies identified in the completed template, in response to question **B1.3 Data Controller(s)**, the research team provided information regarding the data controller, a concept that is specific to GDPR-regulated processing

and therefore inapplicable in the context of a genuinely anonymous study. The indication provided should accordingly be understood not as a designation of a data controller in the legal sense, but simply as an identification of the institution responsible for administering the survey. A further inconsistency was noted in the response to question B3.6 Scope of AI Function, which contains information relating to the use of AI within the study. As clarified in the description of Subsection B3, questions concerning AI applicability are only relevant where the study directly involves the use or development of an AI system. Since the Vignette Study is purely preparatory in nature, aimed at assessing teachers' readiness and acceptance of AI-supported educational technologies, without itself employing or contributing to the development of any AI system, the responses provided to this question fall outside the scope of the present study and should be disregarded for the purposes of AI risk classification.

Analysis of the completion of Section A for the Dashboard Co-design Study (WP1/task T1.3 - Phase 1 and 2)

The "Dashboard Co-design Study" is a small-scale qualitative study involving in-service teachers and educators in the participatory design of the dashboard of the AI-assisted eye-tracking analytics. The activities, which include individual think-aloud sessions (first phase) and focus groups (second phase), are aligned with co-design principles and support the development of a system that is pedagogically relevant and user-oriented. The completed template reflects an overall appropriate ethical framing, and formal ethical clearance has already been obtained from the *Research Ethics Committee (cETO)* of the Open Universiteit, as indicated in **A8.1 Ethical Clearance**, with the relevant documentation attached to the completed template, ensuring transparency and traceability.

Based on the information provided, the following aspects merit ethical consideration.

A first aspect concerns the description of participant well-being in response to question **A4.8 Participant Well-Being**, where mental fatigue is identified as the main potential issue. This assessment appears proportionate to the nature of the activities, which involve cognitive engagement with prototype materials over moderate time periods, and the favourable ethical clearance obtained confirms the adequacy of the approach. Consistently, in **A5.1 Potential Risks**, physical risks in terms of fatigue are identified, and the measures described in **A5.2 Risk Mitigation**, such as allowing

participants to take breaks and ask for clarification, are proportionate to a low-risk study. However, a minor suggestion for future updates of the template is to consider, potential privacy-related risks in the risk assessment, even at minimal level, also based on the data protection safety measures provided in Section B.

A second aspects related to limiting the study participation only to Dutch-speaking teachers, as reported in response to question **A6.5 Languages**, where it is indicated that all consent materials are provided exclusively in Dutch. While this carries some relevance in terms of inclusivity and representativeness for a project aimed at informing the development of educational technologies applicable across diverse European contexts, it does not constitute an ethical concern in itself given the exploratory nature of this phase. The broader project design includes subsequent phases that will engage participants in different national background, thus addressing linguistic and cultural diversity at the consortium level. This contextual limitation can be acknowledged in **A7.3 Fairness and Non-discrimination**, while also emphasizing that, in order to mitigate cultural biases in data representation or usability barriers this study, and the subsequent ones, collect feedback by teachers and educators from different educational levels. Since the study explicitly engages with the principle of human agency and oversight, particularly in response to in **A7.4 Human Agency and Oversight**, where the co-design process is presented as an opportunity for teachers to actively shape how they wish to interact with the system and negotiate levels of automation, this further specification would strengthen the contribution of the Dashboard Co-design Study to the ethical development of the AI-assisted eye-tracking (ET) analytics tool.

Analysis of the completion of Section B for the Dashboard Co-design Study (WP1/task T1.3 - Phase 1 and 2)

With respect to Section B, the processing activities envisaged in the "Dashboard Co-design Study" do not present particular risks from a data protection perspective, given the limited number of adult participants, the nature of the data collected, and the absence of special categories of data. However, the completed template reveals a degree of confusion on the part of the research team regarding certain fundamental data protection concepts. The first issue of note concerns an inconsistency in the response to question **B1.1 Data Status**. The research team correctly acknowledged that the study involves the processing of personal data, specifically audio recordings and

their transcriptions. However, the description of the pseudonymisation process adopted was incorrectly provided in the field reserved for cases where data are to be anonymised during the study, thereby demonstrating a degree of confusion between these two distinct techniques. This should be regarded as a minor formal inaccuracy, given that the team did not claim the data to be anonymous and correctly identified the processing as involving personal data. As clarified in the response to question **B1.5 Security Measures**, the measure adopted is pseudonymisation, not anonymisation. These two concepts are legally and technically distinct: pseudonymisation, as defined in Article 4(5) GDPR, is a security measure that reduces but does not eliminate the risk of re-identification, and pseudonymised data continue to constitute personal data subject to the full application of the GDPR. Anonymisation, by contrast, irreversibly prevents re-identification and places the data outside the scope of the regulation. It is therefore recommended that the description in question **B1.1** be revised to accurately reflect that the data are pseudonymised and remain personal data throughout the processing lifecycle, with pseudonymisation being applied as a technical safeguard rather than as a means of removing the data from the regulatory framework.

Regarding the identification of roles and responsibilities (questions **B1.3** and **B1.4**), the research team has correctly designated the Open Universiteit and the University of Antwerp as joint data controllers pursuant to Article 26 GDPR, which accurately reflects the collaborative nature of the study and the shared determination of the purposes and means of processing. Both institutions have signed a Data Processor Agreement with Copernicus Science Centre.

With respect to question **B1.6 Data Protection Impact Assessment**, the research team has concluded that a DPIA is not required, having assessed that none of the triggering conditions listed in the question are met. This conclusion appears well-founded and proportionate in the specific context of this study. The participants are adults who voluntarily take part in co-design workshops, the number of individuals involved is limited to approximately 18–20 teachers, the data collected consist primarily of audio recordings and transcriptions of think-aloud sessions and interviews, and no special categories of data are processed. The only risk identified by the research team is mental fatigue, which is a low-severity and easily manageable risk in this context. In light of these characteristics, the decision not to conduct a DPIA is consistent with the risk-based approach of the GDPR and does not raise concerns.

With respect to question **B2.2 Right to Withdraw Consent and Data Erasure**, the research team has indicated that withdrawal of consent does not result in the erasure of the participant's data, but has not provided any justification for this position, leaving sub-question d) unanswered. This reflects a common misunderstanding: the fact that Article 7(3) GDPR establishes that processing is lawful until consent is withdrawn does not imply that data collected up to that point may continue to be used. As a general rule, withdrawal of consent should lead to erasure of all data collected, including those gathered prior to the withdrawal, pursuant to Article 17(1)(b) GDPR, which does not render the preceding processing unlawful but requires that the data be deleted once consent is withdrawn. A limitation on this right is permissible under Article 17(3)(d) GDPR only where erasure would render impossible or seriously impair the achievement of the scientific research objectives, and this must be explicitly justified. The research team should have provided a precise and reasoned justification for retaining the data, to be documented both in the template and in the information materials provided to participants.

Regarding question **B2.3 Other Data Subject Rights**, the template indicates that the right of access is addressed in the information sheet provided to participants, without specifying how it can be exercised in practice. Furthermore, the template indicates that the rights of rectification, erasure, and restriction of processing are not permitted. This formulation is legally imprecise: these rights are not simply excluded but may be subject to limitations in the research context under the conditions set out in applicable national implementing legislation pursuant to Article 89 of the GDPR. A more accurate description of the applicable limitations and their legal basis would be useful for complying with GDPR requirements.

With respect to Section **B3 Artificial Intelligence**, the research team has correctly refrained from answering most of the questions in this subsection, with the exception of question **B3.2**, which addresses the study's contribution to AI development. This approach is appropriate: as clarified in the description of Subsection B3 of the present deliverable, the questions in this section are only relevant where the study directly involves the use or development of an AI system. The Dashboard Co-design Study does not employ any AI system, being purely preparatory in nature and aimed at gathering design requirements and teacher feedback that will inform the subsequent development of the AI-assisted eye-tracking analytics tool within the project.

Analysis of the completion of Section A for the Dashboard User Study (WP1/task T1.3 - Phase 3)

The "Dashboard User Study" represents the third phase of the dashboard development process, moving from co-design to empirical user evaluation in realistic conditions. It involves in-service teachers and educators completing information-retrieval tasks on a dashboard prototype while being eye-tracked, and combines behavioral, physiological (eye-tracking), and self-report measures. The study is in still in the planning phase and ethical clearance has not yet been submitted to the *Ethics Committee for Social Sciences and Humanities* of the University of Antwerp (**A8.1**). Therefore, based on the analysis of the submitted template, the following suggestions are offered on relevant aspects that the research team may wish to consider in finalising the protocol and preparing the request for ethical approval.

A first relevant aspect concerns the description of participant well-being and risks in responses to questions **A4.8 Participant Well-Being** and **A5.1 Potential Risks**, where the research team indicates the absence of foreseeable elements that may affect well-being and the absence of potential risks. While the study is clearly low-risk, it does involve eye-tracking equipment, cognitive tasks, and sessions of approximately 1.5 hours, which may be associated with some degree of visual fatigue or cognitive load. From an ethical perspective, this does not raise substantial concerns, but in view of the upcoming submission to the ethics committee, a possible strategy to strengthen this part of the protocol would be to acknowledge these mild and expected forms of discomfort, together with the practical safeguards typically adopted in eye-tracking studies (such as the possibility of breaks, comfort checks during calibration, and the right to withdraw at any time). Similarly, it is appropriate to assess the severity and likelihood of privacy risks and their mitigation strategies. Further evaluation in this direction would likely facilitate the review process and align the protocol with the level of detail generally expected by ethics committees for this type of studies.

Further suggestions concern the questions contained in subsections A7 and A8, which may offer an opportunity for reflection on some aspects of the study itself and its role within the project activities. In particular, the answers to subsection **A7 Ethics of Artificial Intelligence** are very similar to those provided for the previous co-design phases. While this ensures some level of continuity, it also represents a missed opportunity to reflect the specific methodological and analytical features of Phase 3, particularly the use of eye-tracking data, task-based performance measures, and real

interaction with the system. Therefore, while the study maintains a human-centred design perspective, the ethical analysis would benefit from greater specificity, contextualisation, and depth, especially given the more advanced stage of system evaluation. Furthermore, even if the intention to comply with ethical standards is evident, as demonstrated by the indication that ethical clearance will be submitted to the ethics committee of the University of Antwerp (A8.1), also in view of this upcoming submission, it would be beneficial to explicitly highlight in **A8.3 Conflict of Interest** that exclusion of project participants from the sample, as indicated in **A4.4 Exclusion Criteria**, represents an appropriate safeguard against potential conflicts of interest and bias, thus making the connection between the two issues more visible and reinforcing the overall coherence of the ethical approach of the study.

Analysis of the completion of Section B for the Dashboard User Study (WP1/task T1.3 - Phase 3)

With respect to Section B, the "Dashboard User Study", which constitutes third phase of the dashboard research activity, presents a data protection profile that is more complex than that of the preceding phases. While the study is analogous in its objectives to the previous phases, the data collected here are significantly more extensive. In addition to demographic data, behavioural data, audio recordings, and transcripts from think-aloud sessions and semi-structured interviews, this phase also involves the collection of physiological measurements (biometrical measurements are not indicated) and self-reported data from questionnaires. It should be noted, however, that although the template requires researchers to specify the nature of the physiological measurements collected, no such specification has been provided.

As in the preceding studies, a degree of confusion between anonymisation and pseudonymisation is present in question **B1.1 Data Status**, though to a lesser extent: the research team has correctly identified the processing as involving personal data, but has again described the pseudonymisation process in the sub-question dedicated to anonymisation.

Regarding the identification of roles and responsibilities, the two universities have correctly declared the existence of a Joint Controller Agreement pursuant to Article 26 GDPR, and no data processor has been identified. The security measures declared may be adequate, although they should be further detailed and verified in light of the variety and likely volume of the data collected. In this regard, the decision on the need

for a DPIA is noteworthy: although the research team has not selected any of the triggering conditions listed in question **B1.6a** it has nonetheless indicated its intention to conduct a DPIA. This approach is to be commended. As recommended by the Article 29 Working Party in its Guidelines on Data Protection Impact Assessment (WP248), where there is genuine uncertainty as to whether a DPIA is strictly required, it is advisable to conduct one regardless, as this constitutes a proactive and accountable approach to risk management consistent with the principles of the GDPR. Given the variety of data categories collected in this phase, including physiological measurements whose nature has not been fully specified, a DPIA would indeed be a valuable instrument for identifying and mitigating any risks associated with the processing activities.

With respect to question **B2.2 Right to Withdraw Consent and Data Erasure**, the research team has provided a substantially correct response, confirming that withdrawal of consent for data processing results in the deletion of all the participant's data and the cessation of any further use of those data for the study. This approach is fully consistent with the requirements of Article 17(1)(b) GDPR. A limited exception is acknowledged for cases where deletion is no longer reasonably possible at the stage at which the request is made, such as where the research results have already been submitted for publication. This exception is proportionate and consistent with Article 17(3)(d) GDPR, provided that it is clearly communicated to participants in advance. It should be noted, however, that neither of the checkboxes in point c) has been ticked, which represents a minor formal gap that should be corrected for the sake of completeness and clarity of the documentation.

With respect to question **B2.3 Other Data Subject Rights**, the template identifies both the Principal Investigator and the Data Protection Officer (DPO) as contact points for the exercise of data subject rights. While the indication of the Principal Investigator as the primary contact point is correct and appropriate —as the PI is typically the person most familiar with the specific processing activities carried out within the study— the role of the DPO should be understood as distinct. The DPO acts as an independent safeguard for data subjects' rights and should be involved where a participant has not received a satisfactory response from the controller through the designated contact point, rather than being positioned as a primary contact for routine rights requests. This distinction, while not always clearly drawn in practice, is nonetheless relevant for ensuring that the respective roles and responsibilities are correctly understood and communicated to participants. This may be considered a

minor formal inaccuracy that should be clarified in the information materials provided to participants.

Finally, with respect to Section B3 Artificial Intelligence, some responses have been provided to the questions in this subsection. However, these are of limited relevance given that the study does not involve the use or development of an AI system as such, being purely preparatory in nature and aimed at gathering insights that will inform the subsequent development of the AI-assisted eye-tracking analytics tool within the project.

Analysis of the completion of Section A for the Eye Movement Metrics Validation Study (WP1/task T2.3)

The "Eye Movement Metrics Validation Study" represents a key empirical activity within the EYE-TEACH project, involving the collection of eye-tracking and reading comprehension data from children aged 10–13 in school settings in both Spain (University of Valencia) and Finland (University of Turku). The ethical framework reflected in the completed templates shows a generally strong and consistent approach to research involving minors, with particular attention to informed consent, participant well-being, and data protection. At the same time, a limited number of specific ethical aspects merit reflection, especially in view of the upcoming submission to the respective institutional ethics committees (**A8.1**).

A first aspect concerns the different procedures for obtaining children's assent in the two study sites. As indicated in **A6.2 Child/Minor Assent Process**, the University of Turku requires both parental consent and the child's explicit written assent, while the University of Valencia follows local procedures where written parental consent alone is considered sufficient for this age group. This divergence reflects legitimate national regulatory differences and does not in itself constitute an ethical issue. However, from a research ethics perspective, particularly in line with international standards on participation of children aged 10, there is increasing emphasis on recognising children as active participants with evolving autonomy, rather than passive subjects of parental decision-making. For this reason, it may be advisable to include an assent procedure, at least verbal or even written, ensuring that children are explicitly asked whether they wish to participate, and document this process as part of the study procedures, even if not formally required. This would strengthen the harmonisation between sites and

demonstrate alignment with ethical best practices, without imposing additional procedural burden.

A second aspect concerns the communication of individual-level results to teachers, as planned by the research team of Valencia University. Specifically, as indicated in response to question **A5.5 Incidental findings**, individual reading comprehension results (based on PIRLS tasks) may be shared with teachers to enable them to identify potential learning difficulties and take appropriate pedagogical action. This approach is based on the fact that the results derive from standard educational tasks, data are pseudonymised, and teachers are already in a position of legitimate educational responsibility. However, this practice may raise concerns during ethical review, particularly regarding the risk of overinterpretation of research data as diagnostic indicators, as well as the risk that children might confuse research assessment with school evaluations and feel pressured to participate in the study. To mitigate this risk, it would be useful to explicitly clarify both in the protocol and in participant information that these results are not diagnostic and should not be interpreted as such, and to ensure that any feedback to teachers is framed in general and contextualised terms. Furthermore, if possible, it would be useful to define a standardised approach across both sites regarding if, how and when such information is communicated. These adjustments would help maintain a clear distinction between research outputs and educational decision-making, which is often a key point of attention for ethics committees.

Finally, the study demonstrates a strong commitment to inclusive participation, particularly through inviting all students to participate, including students with special educational needs (SEN), and providing appropriate adaptations where necessary, as indicated in **A4.3 Inclusion Criteria**. This is a clear ethical strength and aligns well with principles of equity and non-discrimination. At the same time, some inherent constraint, such as the need for participants to read in the language of instruction (Spanish or Finnish), introduce practical limits to inclusivity. Given that these constraints are methodologically necessary, it may be helpful to acknowledge explicitly that language proficiency is a functional requirement of the task and clarify how this is handled in a non-stigmatizing and transparent manner during recruitment and consent.

Analysis of the completion of Section B for the Eye Movement Metrics Validation Study (WP1/task T2.3)

With respect to Section B, the "Eye Movement Metrics Validation Study" presents several aspects requiring attention, particularly regarding data classification, the allocation of responsibilities between controllers, the adequacy of security measures, and the assessment of the need for a Data Protection Impact Assessment (DPIA).

Regarding question **B1.1 Data Status**, the recurring confusion between anonymisation and pseudonymisation is again present in this template and is further complicated by a significant difference in approach between the two partner institutions leading the two parallel studies. In fact, the University of Turku collects data in fully anonymous form, with no link created between students' identities and their assigned identifiers, and no individual-level results shared with teachers or school officials. The University of Valencia, by contrast, applies pseudonymisation, maintaining a link between participants' identities and their codes in order to allow teachers to receive individual student assessment results. This difference in approach raises an important question of principle: if genuinely anonymous data collection is feasible, as demonstrated by the Turku protocol, then anonymisation should be the preferred approach for all sites, in line with the principle of data minimisation and the provisions of Article 89 of the GDPR, which encourages the adoption of technical and organisational measures that ensure anonymisation where compatible with the research purpose. The planned approach of the Valecia team, which preserves identifiability for the purpose of providing individual feedback to teachers, warrants careful scrutiny. If the provision of individual student assessments to teachers goes beyond the standard assessment practices established within the educational institution and is conducted as part of a research activity, it would require the specific and freely given consent of the participants, especially if they are minors.

However, in the context of a teacher-student relationship, the voluntariness of such consent requires careful consideration due to the structural power imbalance between the parties. As a general principle, the European Data Protection Board has noted in section 3.1.1 of Guidelines 05/2020 on consent (paragraph 16) that where a clear imbalance of power exists, consent cannot as a rule be regarded as freely given. This concern is directly applicable to educational settings: paragraph 20 of the same Guidelines specifically addresses the school context, emphasising that it must be ensured that students are not denied access to education or other services as a

consequence of refusing consent, and that they can decline without suffering any disadvantage or prejudice. It is therefore recommended that this aspect be carefully evaluated before the study proceeds at the Valencia site, and that the research team consult with its Data Protection Officer, as well as with the Ethics Mentor for submitting the request for ethical clearance, in order to assess whether the conditions for freely given consent are genuinely met in the specific institutional and relational context of the study. It should be noted that the concerns outlined above are specifically relevant where consent is relied upon as the legal basis for processing pursuant to Article 6(1)(a) and, where applicable, Article 9(2)(a) GDPR. They would not apply to the same extent if the processing were grounded on an alternative legal basis, such as the performance of a task carried out in the public interest under Article 6(1)(e) GDPR, or on the derogations for scientific research or substantial public interest under Article 9(2)(j) or Article 9(2)(g) GDPR respectively.

With respect to question B1.3, the University of Valencia and the University of Turku are identified as data controllers. However, the significant difference in their respective approaches to data processing (pseudonymisation at Valencia versus full anonymisation at Turku, with correspondingly different regulatory implications) raises a preliminary question as to whether the processing activities conducted at the two sites should be regarded as constituting a single processing operation under joint controllership pursuant to Article 26 GDPR, or rather as two separate and parallel processing activities, each governed independently by its own institutional controller. If the two sites share a common research protocol and jointly determine the purposes and overall means of processing, joint controllership would appear to apply and a formal agreement defining respective responsibilities would be required. If, on the other hand, the divergence in approach is sufficiently substantial to qualify the two activities as independent processing operations, each institution would bear sole responsibility for its own processing, and the regulatory framework applicable at each site would differ accordingly. This issue should be resolved before the two parallel studies begins, as it has direct implications for accountability, applicable legal bases, and data subject rights at each site.

Regarding question **B1.2 Types of Data Collected**, the two studies involve a notably broad and sensitive range of data, including demographic data, behavioural data, physiological and biometric measurements (specifically eye movement metrics such as pupil dilation, fixation durations, scan paths, and blinks) audio recordings, and video recordings including facial images. The collection of this combination of data

categories, several of which are of a particularly sensitive nature, makes the adequacy of the security measures declared in response to question **B1.5** a matter of concern. The only measures indicated are pseudonymisation and secure storage, with no reference to encryption at rest or in transit, access control mechanisms, traceability through logging, or staff training on data protection. Given the volume and sensitivity of the data collected, and the involvement of minors, this limited set of security measures appears insufficient and should be substantially strengthened to meet the requirements of Article 32 GDPR, which mandates the implementation of appropriate technical and organisational measures ensuring a level of security proportionate to the risk.

With respect to question **B1.6 Data Protection Impact Assessment**, the research team has concluded that a DPIA is not required on the grounds that only one of the listed triggering conditions is met, namely the processing of data concerning vulnerable subjects, specifically children. It would appear that the research team does not consider eye-tracking technology as a new technology that may pose risks to individuals' rights and freedoms, given that this condition was not selected in response to question B1.6. However, eye-tracking technology, particularly when used to collect granular physiological measurements such as pupil dilation, scan paths, and fixation durations, is far from a consolidated and risk-free data collection instrument, especially when deployed in educational settings involving minors. When considered in conjunction with the involvement of children as participants and the breadth and sensitivity of the data collected, including biometric measurements, video recordings with facial images, and behavioural data, the overall risk profile of the study is such that a careful and structured evaluation of the potential impact of the processing on participants' rights and freedoms is strongly warranted. Conducting a DPIA would serve precisely this purpose, providing a documented and systematic assessment of the risks involved and of the adequacy of the measures adopted to mitigate them. It is therefore strongly recommended that the research team reconsider its position and proceed with a DPIA, in line with the precautionary approach endorsed by the Article 29 Working Party in WP248 and consistent with the principle of accountability under Article 5(2) GDPR.

Regarding question **B2.2 Right to Withdraw Consent and Data Erasure**, the approach described by both research teams is based on a process of progressive anonymisation: participants may withdraw their consent for data processing until the point at which their data have been fully anonymised, after which the research team

itself would no longer be able to identify which data corresponds to which participant, making erasure technically impossible. This approach is conceptually coherent and, if correctly implemented, would be consistent with Article 17(3)(d) GDPR, which permits limitations on the right to erasure where this would render impossible or seriously impair the achievement of research objectives. However, the description provided in the template lacks sufficient clarity to allow a definitive assessment of its regulatory adequacy. In particular, it is not specified at what stage of the study full anonymisation occurs, what technical process is used to achieve it, or how participants are informed of the point beyond which withdrawal of consent will no longer result in erasure of their data. These aspects should be clarified and explicitly documented, both in the future updates of the template and in the informed consent materials provided to participants, so that the limitations on the right to erasure are transparent, proportionate, and adequately justified.

Finally, with respect to the questions relating to the use of AI in Section B3, the responses provided by the research team are consistent with the preparatory nature of the study. The study does not involve the deployment or development of an AI system as such but contributes directly to the future development of the AI-assisted eye-tracking analytics tool within the project, specifically through the collection of data intended for use in the training and validation of AI models. The responses to the AI-related questions appropriately reflect this role, acknowledging the study's contribution to AI development without claiming that an AI system is currently in use or being developed within the scope of the two parallel studies.

Identifying Common Ethical, Legal and Data Protection Issues

Building on the analyses of the information provided in the Research Protocol Templates completed by the project partners, this section highlights the main ethical, legal, and data protection issues arising from the studies. The aim is to identify cross-cutting aspects that are relevant for ensuring consistent and robust compliance throughout the project. These issues are examined with reference to the main European ethical guidelines and regulatory frameworks, providing a common basis for interpretation and alignment.

Rights and Data Protection of Research Participants, with Particular Attention to Children

All research activities within the EYE-TEACH project involving human participants, particularly children (minors), must be planned and conducted in compliance with ethical guidelines and legal framework governing research involving human subjects at both European and national levels. By integrating GDPR requirements with established ethical principles, researchers can ensure that studies are conducted in a way that is not only compliant, but also respectful, transparent, and proportionate to the risks involved, especially when working with minors.

From a legal perspective, the GDPR provides the primary reference for the processing of personal data in scientific research. While it allows certain derogations from data subject rights (e.g., access, rectification, restriction), Article 89 requires that appropriate safeguards, such as pseudonymisation and data minimisation, are implemented. Researchers should therefore ensure that only strictly necessary data are collected and that technical and organisational measures are in place to protect confidentiality throughout the data lifecycle. Special attention is required when processing children's data. Researchers should verify the applicable national provisions and ensure that parental consent and child assent procedures are aligned with both legal requirements and ethical best practices.

Beyond legal compliance, EYE-TEACH studies should be guided by widely recognised ethical principles originating from international frameworks such as the Declaration of Helsinki and the Belmont Report, and more specifically by European guidance such as Ethics in Social Sciences and Humanities Research. These frameworks emphasise respect for human dignity and autonomy, voluntary and informed participation, protection of vulnerable individuals, minimisation of risks and maximisation of benefits, and respect for privacy and confidentiality. In operational terms, informed consent plays a central role, ensuring voluntary participation, with no coercion or undue influence, and providing clear explanations of study aims, procedures, risks, data use, funding sources, and contact points. Typically, the informed consent materials are written (on paper or online) and adapted to participants' language and comprehension level, unless justified. As emphasized by key ethical guidelines at International level, such as the UN Convention on the Rights of the Child (1989), and at the national level, such as the CNR Child Protection Policy and Code of Conduct (2016), particular care must be taken when involving children in research activities. In

particular, consent procedures are critical and ethical standards require dual consent: parental/legal guardian consent and the child's assent. Even where not legally required, obtaining assent allows to respect the child's evolving autonomy. Information should be provided in an age-appropriate format, and researchers should remain attentive to signs of discomfort or dissent throughout participation. As in the cases of EYE-TEACH studies, when research is conducted in school settings, additional safeguards are necessary. Participants must clearly understand that participation is entirely voluntary, that non-participation or withdrawal has no impact on academic evaluation, and that research activities are independent from school assessment processes. Moreover, particular care should be taken to avoid the unintended disclosure of individual performance data, which could lead to stigma or psychological discomfort. Where results are shared (e.g., with teachers), they should be appropriately contextualised and not presented as diagnostic.

Personal and Biometric Data: Definitions and Regulatory Scope

A preliminary clarification on the notion of personal and biometric data is essential for correctly framing the data protection issues emerging from the completed templates. Under the GDPR, biometric data are defined in Article 4(14) as personal data resulting from specific technical processing relating to the physical, physiological or behavioural characteristics of a natural person, which allow or confirm the unique identification of that person, such as facial images or dactyloscopic data. These constitute a special category of data under Article 9 GDPR, subject to enhanced protection. However, the European Data Protection Board has clarified (Guidelines 3/2019 on processing of personal data through video devices, par. 74) that ordinary photographs or video recordings do not automatically qualify as biometric data in the special category sense, unless they are processed through specific technical means enabling unique identification. The AI Act adopts a slightly different definition: Article 3(34) defines biometric data as personal data resulting from specific technical processing relating to the physical, physiological or behavioural characteristics of a natural person, such as facial images or dactyloscopic data, without the requirement of unique identification. This broader formulation likely reflects the specific risks associated with the use of biometric data in AI systems, where even data that do not serve identification purposes may nonetheless carry significant privacy implications and be susceptible to re-identification when processed by AI models. Researchers within the EYE-TEACH project should be aware of this definitional distinction and

ensure that the regulatory framework applicable to their specific processing activities, whether under the GDPR, the AI Act, or both, is correctly identified.

Figure 1 shows that EYE-TEACH studies reported up to now rely most heavily on demographic and audio data (each used in three studies), with behavioral, physiological/biometric, and semi-structured interview transcription present in two studies apiece, and video and self-reported measures used least (one study each). This means that there is a mix of data used in the project, including background information and interview transcripts with objective behavioral and biometric signals (eye-tracking, audio). In particular, the inclusion of biometric, audio, and video data deserves particular attention regarding ethical and privacy requirements.

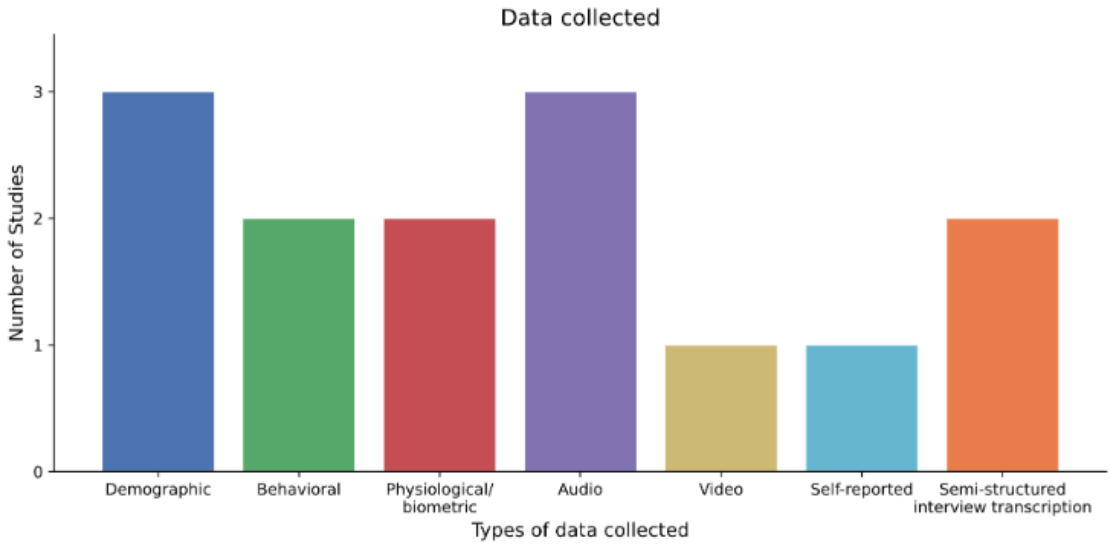

Figure 1. Types of data collected in the different studies.

The Distinction Between Anonymisation and Pseudonymisation

A recurrent issue across the completed templates is the confusion between anonymisation and pseudonymisation. This distinction is of fundamental legal significance and must be clearly understood by all researchers involved in data processing activities within the project. Pseudonymisation, as defined in Article 4(5) GDPR, consists in the processing of personal data in such a manner that they can no longer be attributed to a specific data subject without the use of additional information kept separately. Pseudonymised data remain personal data and are fully

subject to the GDPR. Anonymisation, by contrast, is an irreversible process that renders re-identification impossible, placing the data outside the scope of the regulation entirely. The Court of Justice of the European Union has provided important guidance on the conditions under which data may be regarded as truly anonymous in its judgment of 4 September 2025 in Case C-413/23 P (commonly referred to as the Deloitte judgment), clarifying that the assessment of anonymity must take into account all means reasonably likely to be used for re-identification, including cross-referencing with other available data sources. The relevance of this distinction has also been acknowledged at the legislative level: the concept of the subjective nature of anonymised and pseudonymised data has been addressed in the proposed EU Omnibus simplification regulation, which includes targeted amendments to the GDPR framework and is currently under discussion. Should this proposal be adopted in its current or a substantially similar form, it would further reinforce the importance of correctly qualifying the nature of the data processed. It follows that the mere absence of direct identifiers is not sufficient for data to be considered anonymous: a careful assessment must be conducted to verify that re-identification through the combination of available data, including publicly accessible sources, is not reasonably possible. In this regard, researchers may usefully refer to the anonymisation techniques documented by the Article 29 Working Party in Opinion 05/2014 on anonymisation techniques (WP216), which provides a structured overview of established methods and their respective strengths and limitations. Given the frequency with which this distinction has been misapplied in the templates examined, it is recommended that future revisions of the Research Protocol Template include a dedicated explanatory note on this issue, and that the matter be explicitly addressed in upcoming training or consortium meetings.

Anonymisation and the Regulatory Implications for Consent

A further consequence of the distinction outlined above concerns the legal requirements applicable to the processing. Where data are genuinely and verifiably anonymous, the GDPR does not apply, and it is therefore not necessary to obtain consent for data processing. However, it remains good practice, and a matter of transparency and trust, to provide participants with a brief informational notice explaining how anonymity is ensured, through which methods or technical measures, and why re-identification is not possible. This allows participants to understand the

conditions under which their data are used and to make an informed decision about their participation in the study, even in the absence of a formal consent requirement.

Focus on the Specific Processing Activities

When addressing the data protection aspects of their studies, researchers should shift their focus from the study as a whole —its scientific objectives, expected benefits, and broader societal value— to the specific processing activities that the study entails. This means identifying and describing, with precision, what data are collected, for what specific purpose, by whom, through which means, for how long, and under what conditions they are shared, transferred, or disposed of. This processing-centred perspective is essential for several reasons. First, it enables a more accurate and complete risk assessment, since risks to individuals' rights and freedoms arise from the processing activities themselves rather than from the study's scientific merits. Second, it allows participants to receive clear and meaningful information about how their data are handled, rather than a general description of the research context. Third, it enables the Data Protection Officer, where designated, to effectively assess the compliance of the processing activities and to provide informed guidance to the research team. A study may be scientifically valuable and ethically sound while still presenting significant data protection risks that require specific mitigation measures: it is only by focusing on the processing that these risks can be properly identified and addressed.

Systematic Underestimation of Risk and Inadequacy of Security Measures

The underestimation of risks associated with the processing of personal data is a recurring tendency in the research sector. Researchers are naturally and primarily focused on the scientific objectives of their studies, and data protection considerations, while increasingly recognised as important, do not always receive the same level of attention and expertise as the methodological and analytical dimensions of the research. The EYE-TEACH project is no exception to this pattern, as evidenced by the analysis of the completed templates. In **Figure 2** the main risks foreseen for study participants are summarized. Physical risks are noted in two studies and psychological and social risks noted in one study each. One study reported no risks while economic, privacy, and discrimination risks are not explicitly flagged. Physical

risk appears minimal (e.g., low-risk equipment like eye-trackers) but should still be managed via safety checks and comfort monitoring. Psychological risk (cognitive load, potential stress during tasks or recall interviews) and social risk (embarrassment, reputational effects from transcripts or recordings) are present and warrant careful protocol design, especially for children. Although privacy and discrimination are not counted on the graph, they remain important given audio, video, biometric, and interview data and the AI modelling: risks include re-identification, sensitive inference, and biased model outputs.

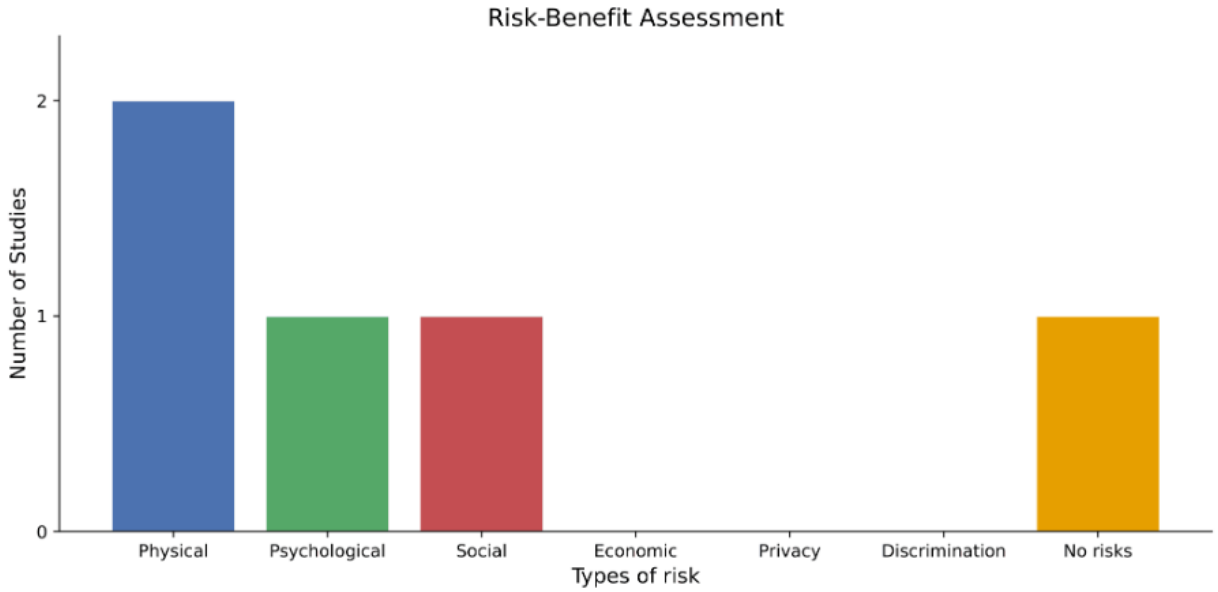

Figure 2. Foreseeable risks to participants identified in the studies.

In several cases, the security measures declared appear insufficient relative to the nature, volume, and sensitivity of the data collected. A particularly notable observation is that none of the studies included in the project has indicated either encryption at rest or encryption in transit as a security measure. With regard to encryption in transit, it should be recalled that HTTPS is today considered a mandatory requirement for all websites and web applications, irrespective of whether personal data are processed: it serves the dual purpose of ensuring the confidentiality of communications between the user and the service, and of guaranteeing the authenticity of the service itself, thereby protecting users from interception and impersonation attacks. In the context of processing personal data, its implementation is therefore not merely a best practice

but a baseline technical obligation under Article 32 GDPR. It should however be noted that this does not necessarily mean that encryption in transit is not actually implemented in the research environments concerned. Rather, it is likely that researchers are simply unaware of the technical infrastructure in place at the institutional or platform level and have therefore not reflected it in their responses. Researchers are accordingly encouraged to verify the actual security measures implemented in their specific environment and to ensure that these are accurately and completely documented in the template, including measures that may be applied automatically by the systems or platforms used.

The Role and Importance of the DPIA

The underestimation of risk is closely related to the tendency, observed in several of the completed templates, to conclude that a Data Protection Impact Assessment is not required. It is important to emphasise that a DPIA is not merely a formal compliance exercise: its primary purpose is to prompt the data controller, in the context of research activities, the responsible researchers and their institutions, to systematically reflect on the potential risks of the processing and on the impact that the materialisation of those risks could have on the rights and fundamental freedoms of the individuals concerned. In this sense, a DPIA is a valuable governance instrument even where its outcome is a confirmation that the residual risks are acceptable. It is worth noting that at least one study within the project has adopted a commendably precautionary approach, electing to conduct a DPIA despite uncertainty as to whether one was strictly required. This approach is consistent with the recommendations of the Article 29 Working Party in WP248 and should serve as a model for the other studies presenting a comparable risk profile.

In the Research Protocol Templates, we collected information about high risk factors of the studies that deserve attention. If at least two of the factors are foreseen, the DPIA is requested. According to what reported in the templates, two studies marked “None of the above,” one study flagged for “Data concerning vulnerable subjects,” and one for “new technologies that may pose risks” (**Figure 3**). Since no study has selected more than one risk, according to this initial assessment, any DPIA should be performed. However, this aspect will be carefully evaluated and discussed with the partners in the next period of the project.

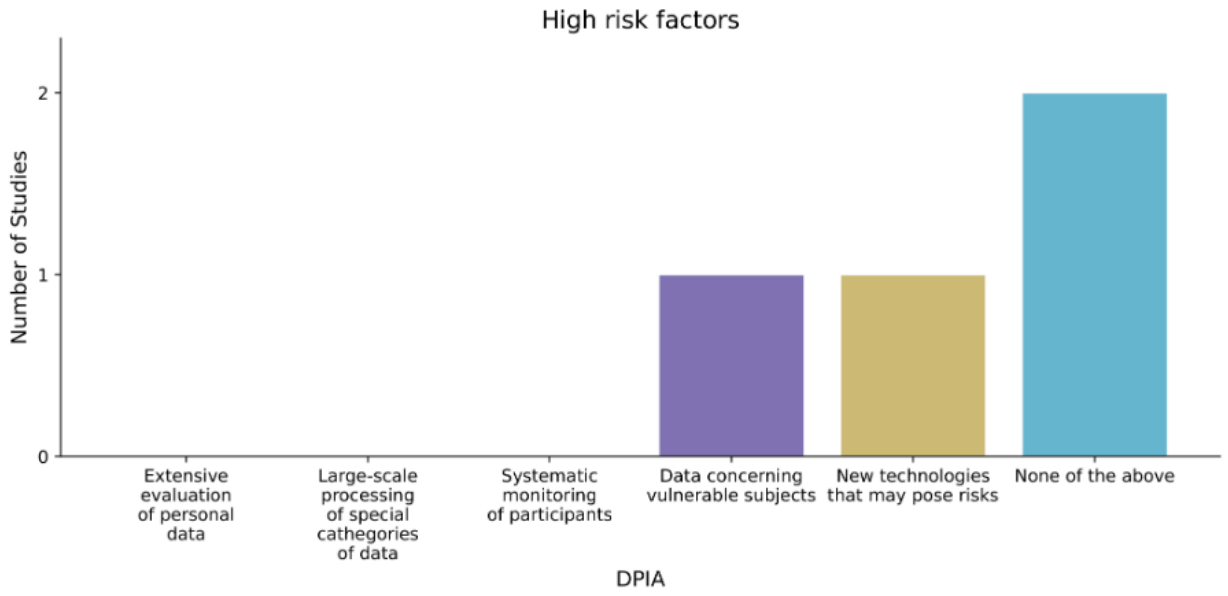

Figure 3. Risk factors that deserve attention for the requirement of the DPIA.

Exercise of Data Subject Rights and Withdrawal of Consent

Another recurring area of uncertainty concerns the exercise of data subject rights, and in particular the consequences of withdrawal of consent. A common misunderstanding observed across several completed templates is the assumption that, since Article 7(3) GDPR establishes that processing is lawful until consent is withdrawn, data collected up to that point may continue to be used after withdrawal. This interpretation is incorrect: as a general rule, withdrawal of consent should lead to the erasure of all data collected, including those gathered prior to the withdrawal, pursuant to Article 17(1)(b) GDPR. The lawfulness of the processing carried out before withdrawal is not in question; what is required is that the data be deleted once consent is withdrawn. Derogations from this rule are permissible in research contexts under Article 17(3)(d) GDPR, where erasure would render impossible or seriously impair the achievement of the research objectives. However, where this exception is invoked, researchers are required to provide a clear and explicit justification, and participants must be informed in advance of the conditions and limitations applicable to the exercise of their right to erasure. Similarly, where other data subject rights, such as rectification, restriction of processing, or data portability, are not fully available in the research context, this must be explained to participants with a reference to the

applicable legal basis for the limitation, rather than simply stated as a fact without further justification.

Applicability of the AI Act and Risk Classification

With regard to the AI Act, it should be noted that while research exemptions are provided under Articles 2(6) and 2(8) of the regulation, the EYE-TEACH project is explicitly oriented towards the development of a tool intended for eventual market deployment. This means that, even during the current research and development phase, the requirements of the AI Act should be taken into consideration from the outset, in line with the principle of ethics and privacy by design adopted within the project. It should however be noted that, even where the project could in principle benefit from the research exemption provided under Article 2(8), this exemption is conditional: it applies only insofar as the experimentation is not conducted under real-world conditions. It is therefore essential that researchers ensure that all experimental activities —including those conducted in regular classrooms during ordinary lessons— are structured in a manner that qualifies as a "laboratory or otherwise simulated environment" within the meaning of the regulation. This requires in particular that all participants, including both teachers and students, are fully aware of the experimental nature of the activity and that appropriate procedural safeguards are in place to clearly distinguish the experimental context from ordinary educational practice. This distinction is of practical relevance and should be carefully considered when designing and planning the experimental activities of the project.

A particularly critical aspect of AI Act compliance concerns the prohibition, established in Article 5(1)(f), on AI systems that infer the emotions of natural persons in educational institutions. For the AI-assisted eye-tracking analytics tool developed within the project to avoid classification as a prohibited system, it is essential that developers identify and document, already at this stage, the specific measures implemented to ensure that the system does not infer or reveal emotional states of users. This requires not only a technical design choice but also a clear and verifiable declaration of the functions performed by the system and the nature of the inferences it produces.

In the absence of emotion inference, the risk classification of the tool depends significantly on whether its function is considered to involve the profiling of individual students. This is a question that deserves careful attention. If the assessments

produced by the system are discrete and temporally bounded —that is, if they evaluate learning outcomes at specific points in time without being retained and aggregated into longitudinal profiles of individual students— the tool may be regarded as not involving profiling within the meaning of the regulation, and could potentially qualify for a moderate risk classification under Article 6(3) of the AI Act, as discussed in the preceding sections of this deliverable. If, on the other hand, individual assessment results are stored over time and subjected to longitudinal analysis, the tool would constitute a profiling system, which would place it unambiguously within the high-risk category established by Annex III, paragraph 3(b) of the AI Act. It should be emphasised that longitudinal profiling is not prohibited as such: it would simply entail a higher risk classification and correspondingly more stringent regulatory obligations. The design choices made in this regard should therefore be deliberate, clearly documented, and explicitly reflected in the risk classification of the system.

Whether the tool ultimately falls within the high-risk or moderate-risk category will depend significantly on the extent to which its outputs influence the final assessment of individual students. This is because it is one of the key factors considered under Article 6(3) of the AI Act when determining whether a system poses a significant risk of harm. Therefore, it is important that the intended outputs and their role in the educational process are clearly defined at the design stage. However, it should be acknowledged that the actual impact of the tool's outputs on individual assessment decisions will depend considerably on the context in which the tool is deployed, and how it is used once it is on the market. These are factors that cannot be fully determined at the current stage of development. This further highlights the importance of designing the system with sufficient flexibility and transparency. This will enable those responsible for deployment to clearly understand the nature and limitations of the tool's outputs. It will also ensure that meaningful human oversight is maintained in any decision-making process affecting individual students.

Should the tool be classified as high-risk, a set of mandatory obligations would apply under Section II of Chapter III of the AI Act (Articles 8 to 15), covering requirements such as risk management systems, data governance, technical documentation, transparency, human oversight, accuracy, robustness, and cybersecurity. Among these obligations, particular relevance for the present project attaches to the conduct of a Fundamental Rights Impact Assessment (FRIA), as provided for in Article 27 of the regulation. The FRIA is specifically designed to assess the potential impact of a high-risk AI system on the fundamental rights of the individuals affected by its use.

Given the substantial overlap between the subject matter of a FRIA and that of a DPIA —both instruments being concerned with the identification and mitigation of risks to individuals arising from the processing of personal data and the use of AI— it would be strongly advisable to conduct the two assessments in an integrated manner. A coordinated approach would avoid duplication of effort, ensure consistency between the two assessments, and produce a more comprehensive and coherent picture of the risks associated with the system and the measures adopted to address them. The correct classification of the tool under the AI Act remains a matter requiring ongoing attention and should be formally addressed in the subsequent phases of the project. **Figure 4** presents a flowchart summarising the risk classification assessment described above.

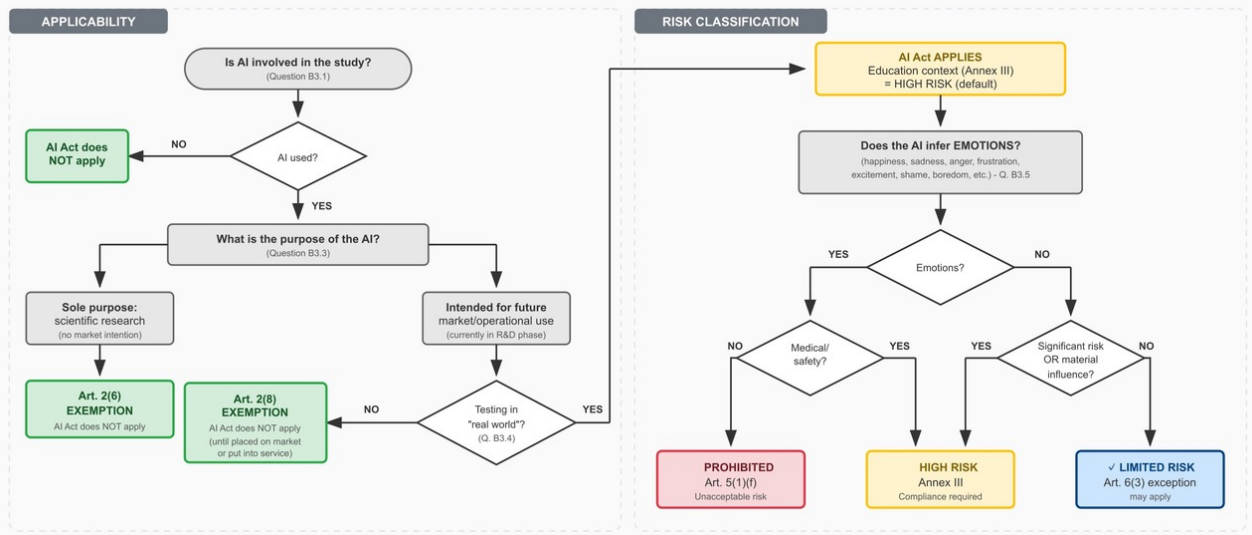

Figure 4. AI Act applicability and Risk Classification Flowchart

According to the information provided in the templates completed so far, **Figure 5** shows that in the EYE-TEACH studies AI is mainly used to make learning-related inferences (2 studies), while physical/mental state and emotional-state inferences are not reported. Based on this preliminary assessment, the AI-assisted eye-tracking analytics under development cannot be considered as prohibited since no emotional inference is performed. However, non-sensitive inferences about cognitive state or learning progress can become high-risk if they are used to profile, evaluate, or make decisions that affect participants (e.g., judgments about competence, remediation, or

surveillance) and deserves careful attention so that the mandatory obligations of the AI Act are applied.

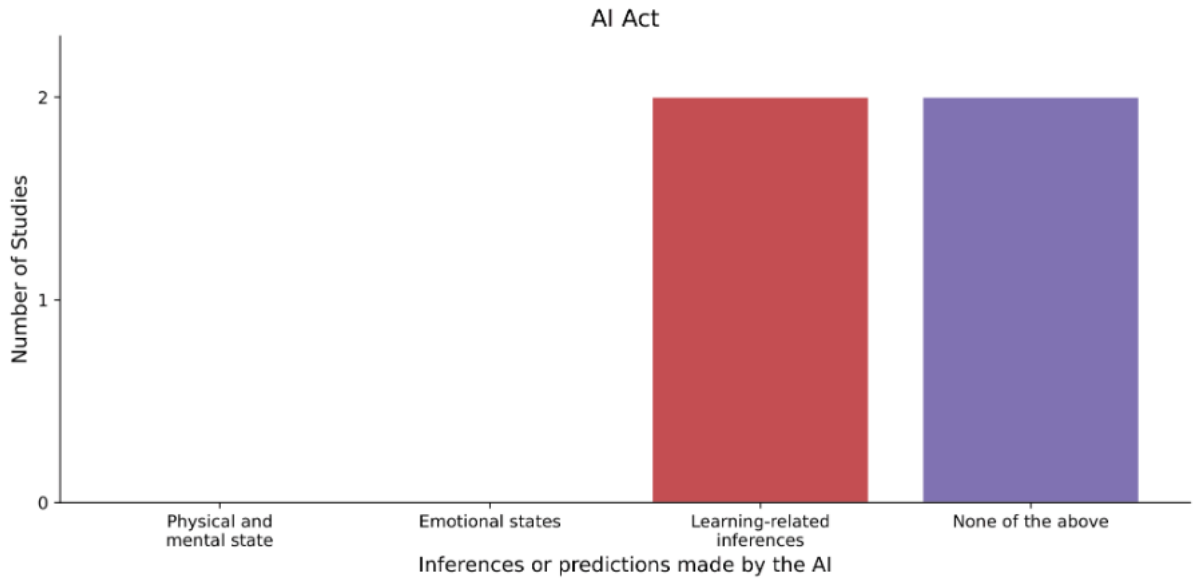

Figure 5. Inferences and predictions that might be challenging according to the AI Act.

Conclusions and Future Work

This deliverable presented the development, implementation, and initial application of the EYE-TEACH Research Protocol Template as a core instrument to support ethical and legal compliance across experimental studies involving human participants. The template was conceived following an ethics and privacy by design approach, integrating ethical consideration and legal requirements from the earliest stages of study planning, rather than treating them as ex post obligations. Its iterative development, through internal drafting by the CNR team, consultation with project partners, and validation by the Ethics and Legal Advisory Board (ELAB), has resulted in a structured, user-oriented tool that is both comprehensive and adaptable to different research contexts.

The dissemination of the template among project partners is playing a key role in promoting shared ethical and legal awareness across the consortium. Beyond its function as a reporting instrument, the template is a practical support tool for researchers, guiding them in systematically identifying potential risks, clarifying

responsibilities, and aligning their study designs with applicable regulatory frameworks, including the GDPR and the AI Act. The structured workflow for submission, review, and revision strengthens this process, enabling continuous dialogue between researchers and the ethics team and supporting the preparation of materials for institutional ethics approvals. In this sense, the template, also included as an annex to this deliverable, represents a reusable tool that could be adopted in similar research projects involving human participants for the development of AI-based systems.

The analysis of the completed templates has provided valuable insights into the main ethical and legal issues emerging across the studies. Overall, the studies demonstrate a generally strong and proportionate ethical approach, with appropriate attention to informed consent procedures, participant well-being, and the protection of vulnerable groups, particularly children. At the same time, the analysis has highlighted a number of recurring aspects that require careful consideration. These include, among others: the distinction between anonymisation and pseudonymisation; the need for explicit and robust data security measures; the assessment of when a Data Protection Impact Assessment (DPIA) is required; the management of data subject rights, especially withdrawal of consent; and the importance of maintaining a clear separation between research activities and institutional roles (e.g., in school settings). In addition, the analysis has underlined the relevance of early reflection on AI-related ethical issues, even in preparatory studies, particularly with regard to fairness, transparency, and future system design choices. These findings will inform the final recommendations to be developed at the end of the EYE-TEACH project, aimed at consolidating a coherent and operational framework for ethical and legal compliance in research involving AI and human participants in educational contexts.

Further iterations of the template and continued exchanges with project partners are already planned. This is particularly relevant for studies that are still in the planning phase, especially within WP2, where additional refinements may be needed before submission to ethics committees. At the same time, the use of the template will be progressively extended to researchers directly involved in the development of the AI system in WP3, in close coordination with partners responsible for data collection and system testing activities. This will ensure that ethical and legal considerations remain fully integrated throughout the entire lifecycle of the project, from data collection to system development and validation.

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Annex: EYE-TEACH Research Protocol Template (v2.1)

EYE-TEACH

Research Protocol Template

Responsible Organisation

Consiglio Nazionale delle Ricerche (CNR)

Funded by the European Union

Funded by the European Union. Views and opinions expressed are however those of the authors only and do not necessarily reflect those of the European Union or the European Research Executive Agency (REA). Neither the European Union nor the granting authority can be held responsible for them.

Document History

Version	Date	Action	Authors
v1	20/12/2025	First draft of the research protocol template	Ludovica Marinucci, Marco Annoni, Raffaele Conte, Cinzia Caporale (CNR)
v2	23/02/2026	Major revisions based on feedback from partners	Ludovica Marinucci, Raffaele Conte, Marco Annoni, Lucia Billeci (CNR)
v2.1	06/03/2026	Minor revisions to Section A7 based on feedback from the ELAB board	Ludovica Marinucci (CNR)

Table of Contents

General Introduction

This research protocol template has been developed to support the coordinated and ethically responsible implementation of research activities carried out within the European project EYE-TEACH. As a multi-partner consortium bringing together universities, research institutes, technological developers and educational organisations, EYE-TEACH integrates diverse methodological approaches and disciplinary perspectives to develop a novel AI-based eye-tracking system for educational contexts. Achieving this goal requires the systematic collection, processing and analysis of human-participant data, including minor students, to design and validate the AI system. The complexity and heterogeneity of these experimental activities make it essential to adopt a harmonised internal framework that ensures scientific robustness, methodological transparency, and full compliance with the highest ethical, legal, and data protection standards applicable in the European Union. This template, therefore, serves as a shared framework through which each Principal Investigator or equivalent can describe, justify, and document the key features of the planned study. Because experimental activities in EYE-TEACH vary significantly, the template is designed to capture this diversity while maintaining a common evaluative lens. It provides a structured tool for identifying the scientific objectives, methodological strategies, and technological implementations that define each study, thus allowing for the assessment of their ethical sustainability both individually and as a part of the collective work within the project. By requiring all partners to complete this template, the EYE-TEACH project aims to ensure that every study is grounded not only in scientific validity but also in ethical integrity and legal compliance.

A central motivation for creating this research protocol template lies in the project's explicit engagement with human participants, especially minors. Such involvement requires not only scientific justification but also rigorous protection of participants' welfare, autonomy, and privacy. Researchers are therefore invited to articulate clearly the scientific motivations behind the participation of human subjects, the expected benefits of the study, and any potential risks. They must also demonstrate that the study design and methodology are robust, proportionate, and aligned with established ethical standards. To this end, the template contains sections dedicated to fundamental safeguards in research ethics, in particular informed consent procedures aimed at ensuring a full understanding of the purposes and modalities of participation and data processing, with a particular focus on the procedures for obtaining informed consent when minors are involved. Given the project's emphasis on developing AI-enhanced technologies, the template also offers a structured space to explain the specific artificial intelligence techniques and machine-learning models used. Researchers are asked to outline how these technologies interact with participant data, what safeguards are implemented to mitigate algorithmic biases, and how they adhere to the principles of trustworthy AI. These ethical requirements reflect the project's commitment to aligning with key European guidelines and regulatory frameworks, ensuring that the development of AI systems remains oriented toward the protection of fundamental rights, especially in sensitive contexts such as education. By articulating the rationale, methodologies, and ethical considerations of each study, the template both strengthens the project's scientific foundation and reinforces its commitment to trustworthy, human-centred technological advancement.

It is important to emphasise that this research protocol template, created specifically for the EYE-TEACH project, does not replace the official documentation required by national ethics committees, nor does it serve as a standalone ethics approval form. Furthermore, it does not substitute any documentation required under applicable European or national regulations, such as a Data Protection Impact Assessment (DPIA) under the GDPR or any other compliance documentation mandated by EU or local law. Instead, it functions as an internal harmonisation and quality assurance tool. It facilitates ethical reflection and the preparation of official documentation while also allowing the EYE-TEACH consortium to maintain a coherent overview of all research activities involving human participants, the data collected and the measures adopted to protect participants' rights. To this end, Principal Investigators remain responsible for preparing and submitting the documentation required by their organisation or local ethics committee and are recommended to attach all approved ethical clearances to the completed template, providing a summary of the main point covered in the original documents in the dedicated section. Furthermore, as it is good practice to provide data subjects with a summary of the DPIA (if one is to be conducted), Principal Investigators are asked to attach it, together with any supplementary materials deemed relevant. This includes the Participants' Information Sheets, Informed Consent Forms and, when minors are involved, Assent Forms and Parental Consent Documents (see the Attachments Checklist).

Instructions for Completion

Please complete all questions relevant to the specific study for which this template is being submitted. For questions that are not applicable to your study, clearly indicate "Not Applicable (N/A)". Instead, if a question is relevant but the information is not yet fully defined, provide the most accurate provisional information available. If a complete or even provisional answer cannot be provided at this stage, indicate "To be defined". For Yes/No items, select the appropriate option and provide additional details where requested.

A first completed draft of the template must be submitted to the CNR team in Word format. Following an initial exchange between the Scientific Responsible(s) of the study and the CNR contact persons for Sections A and B of the template, the revised version of the document must be sent to the CNR team by email in PDF format, dated and signed by the Scientific Responsible(s) of the study.

Section A: Research Ethics and Ethics of AI

A1. STUDY IDENTIFICATION

1.1 Study Title
Provide the full title of the research study, specifying whether it is provisional or final.

1.2 EYE-TEACH Task(s) / Work Package(s)
Indicate the task and WP to which the study refers and specify whether the study is related to other tasks and WPs, if applicable.

1.3 Principal Investigator (PI)
Name, institution, department, email.

1.4 Co-Investigators
List all co-investigators with their affiliations, roles and involvement in the study. Repeat for each.

1.5 Consortium Partner Institutions
List all partner institutions involved, their legal status, and the responsible PI at each site.

1.6 Expected Duration
Start date and end date.

1.7 Funding Source(s)
Specify whether the study is supported by funding sources other than the European grant for EYE-TEACH project.

A2. SCIENTIFIC BACKGROUND AND RATIONALE

2.1 Abstract
Provide a summary of the study (max 300 words) including objectives, methods, and expected outcomes.

2.2 Scientific Background
Describe the theoretical framework and relevant literature, including the gap addressed by the study.

2.3 Research Questions / Hypotheses
Explain the research questions or hypotheses to be tested.

2.4 Expected Scientific Contribution
Describe the new knowledge generated by this study and explain how it contributes to the goals and overall purpose of the EYE-TEACH project.

2.5 Study Pre-registration
Indicate whether the study is pre-registered and specify the platform used.

A3. STUDY DESIGN AND METHODOLOGY

3.1 Study Design
Describe the study design: experimental, quasi-experimental, correlational, longitudinal, cross-sectional, mixed-methods, etc.

3.2 Variables
Identify independent, dependent, and control variables. Describe experimental control.

3.3 Procedures
Provide a step-by-step description of what participants' experience, from recruitment to debriefing. Include estimated time commitment.

3.4 Materials and Instruments
List all questionnaires, tasks, stimuli, software, and equipment. Provide references for validated instruments and attach copies if possible.

3.5 Setting(s)
Specify where the study takes place (e.g., laboratory, online, field setting, multiple sites).

3.6 Randomization / Counterbalancing
If applicable, describe randomization procedures and counterbalancing strategies.

3.7 Statistical Analysis Plan
Briefly describe planned analyses.

A4. STUDY PARTICIPANTS

4.1 Target Population
Describe specific individuals or groups who share characteristics relevant to the study.

4.2 Sample Size and Justification
State the planned sample size and provide power analysis or other justification.

4.3 Inclusion Criteria
Explain all criteria that participants must meet to be included.

4.4 Exclusion Criteria
Explain all criteria that would exclude potential participants.

4.5 Recruitment Strategy

Describe how participants are identified and recruited.

4.6 Are the participants volunteers?

☐ Yes ☐ No

If yes, indicate whether any form of compensation is provided and describe the type of compensation or incentives offered (e.g., subscription, vouchers, etc.), including a justification of the amount and the decision to provide it to participants.

4.7 Are they children/minors?

☐ Yes ☐ No

If yes, specify the age range of the children involved, justify their inclusion in the study, and describe how they are recruited.

4.8 Participant Well-Being

Describe the safety measures put in place before, during and after the study. Explain procedures to prevent participants, particularly children/minors, from experiencing discomfort or being subjected to any form of coercion or undue inducement to participate in the study.

A5. RISK-BENEFIT ASSESSMENT

5.1 Potential Risks

Specify all foreseeable risks to participants and identify the applicable risk categories from those listed below:

☐ Physical risks (discomfort, fatigue, health effects from equipment)
☐ Psychological risks (stress, anxiety, emotional distress)
☐ Social risks (stigmatization, damage to reputation)
☐ Economic risks (costs, loss of employment opportunities)
☐ Privacy risks (unauthorized access, re-identification, unintended disclosure)
☐ Discrimination risks (unfair treatment based on inferred characteristics)
☐ Other risks specific to your study

Rate severity (low/medium/high) and likelihood (unlikely/possible/likely) for each identified risk.

5.2 Risk Mitigation
Explain what measures are taken to minimize risks.

5.3 Potential Benefits
Describe any direct benefits to participants and broader scientific/societal benefits.

5.4 Risk–Benefit Ratio
Explain why the potential benefits justify any risks involved.

5.5 Incidental findings
Provide details on your unexpected findings policy.

A6. INFORMED CONSENT AND ETHICS

6.1 Adult Consent Process
Describe how informed consent is obtained (e.g., signed on paper or by clicking an online form) and list all information provided to participants prior to consent. For minor participants, specify the procedure for obtaining parental/legal guardian consent.

6.2 Child/Minor Assent Process
If applicable, describe how the child/minor's willingness to participate in the study is taken into account and explain how his/her assent is obtained. List all information provided to participants prior to assent.

6.3 Comprehension Check
If applicable, explain all the strategies (e.g., using visual aids) to ensure that participants, especially children, understand what they are consenting to.

6.4 Right to Withdraw

Explain how participants are informed of their right to withdraw from the study at any time.

6.5 Languages

Indicate in which language(s) the consent materials are provided.

6.6 Documentation (select the appropriate option)

☐ Information sheet(s) and consent form(s) have already been provided and signed by participants (attached)

☐ Information sheet(s) and consent form(s) have been developed but not yet distributed to participants (attached)

☐ Information sheet(s) and consent form(s) are being developed.

A7. ETHICS OF ARTIFICIAL INTELLIGENCE

7.1 Contribution to AI Development and Use

Explain how the involvement of human participants in the study contributes to the preliminary design, development and/or improvement of the AI-assisted ET-analytics tool in education (e.g., through teacher surveys, co-design sessions, eye-tracking data collection in laboratory or real-world learning environments, etc.).

7.2 Transparency and Explainability

Describe all information provided to study participants regarding their involvement in the development of the AI system and/or the use of AI models or tools during the study, including how they function.

7.3 Fairness and Non-discrimination

Explain what strategies are in place to prevent and mitigate potential biases and discriminations that may arise in the development and/or use of the AI system (e.g., algorithmic and/or eye movements biases related to cognitive, physiological, cultural, environmental, technological factors, etc.)

7.4 Human Agency and Oversight

Explain how AI algorithmic decisions may impact study participants and future users of the AI system. If applicable, explain whether the study contributes to the inclusion of human human oversight mechanisms for algorithmic decisions in the development of the AI system.

7.5 Safety and Accountability

Describe whether and how the study contributes to the development of a safe AI system, ensuring the correct functioning and reliability of the model/system for its intended purposes and for the target population.

7.6 Social Impact

Describe whether and how the study contributes to understanding the impact of the AI system on education and the school environment, including the work of teachers. Explain whether new (digital) skills of teachers and students are being promoted or whether there could be the risk of deskilling.

A8. RESEARCH ETHICS AND INTEGRITY

8.1 Ethical clearance

Is ethical approval being developed or has it been submitted or obtained from the University Ethics Committee of the study's Principal Investigator?

☐ Yes ☐ No

a) If yes, provide details. If obtained, attach the ethical approval. Also, indicate whether any changes have occurred that require reporting to the ethics committee (e.g., the decision to offer incentives to study participants, etc.).

b) If not, explain why such approval is not required.

8.2 Ethics mentor(s)

Name, institution, department, email.

8.3 Conflicts of Interest

Declare any potential conflicts of interest between researchers, teachers, students, institutions, companies, etc.

8.4 Results Dissemination

Describe the planning on dissemination of the study results and conclusion, including to study participants.
8.5 Publication Plans *Describe the publication plans for the study results, specifying whether they will be made available as open access.*
8.6 Potential Misuse *Describe any potential risks of misuse of the data collected and/or the results obtained, and specify the security measures in place to prevent such misuse.*
8.7 Dual-use Concerns *Assess whether the research results and/or developed technologies could potentially be used in harmful, dangerous, or military-related ways, and describe the strategies in place to prevent such misuse.*
8.8 Other Ethical Issues *Describe any additional ethical considerations not covered above (e.g., cultural, social, or political sensitivities) that may require attention.*

Section B: Data Protection and AI Risk Classification

B1. DATA PROTECTION AND MANAGEMENT

1.1 Data Status

Does the study involve data relating to natural persons?

☐ Yes, personal data (directly or indirectly identifying individuals)

☐ Yes, but data is anonymous at source (never linked to identifiable individuals)

☐ Yes, but data will be anonymized during the study

☐ No

a) If data is considered anonymous at source, explain why it cannot be linked to individuals:

b) If data will be anonymized, describe the anonymization process (note: anonymization itself is a processing operation):

c) If the study does not involve data relating to natural persons, skip to Section B3.

1.2 Types of Data Collected

List all types of data collected from participants:

☐ Demographic data (age, gender, education level, etc.)

☐ Behavioral data (task performance, responses, etc.)

☐ Physiological/biometric measurements – specify:

(e.g., eye movement, pupil dilation, fixation duration, scan paths, blink rate, EEG, skin conductance, heart rate, etc.)

☐ Audio recordings

☐ Video recordings (including facial images)

☐ Self-reported data (questionnaires, interviews)

☐ Other:

ROLES AND RESPONSIBILITIES

1.3 Data Controller(s)

Who is responsible (the data controller) for determining how and why personal data is processed? If there is more than one data controller, have they established an agreement between them defining their respective responsibilities with regard to the data subjects?

1.4 Data Processor(s)

Are any parties or third parties processing data on behalf of the controller (e.g. technology or equipment providers, software developers, etc.)? If so, please specify. Are there written agreements in place?

DATA PROTECTION SAFEGUARDS

1.5 Security Measures

What measures are implemented to ensure data security at rest and in transit?

☐ Encryption at rest

☐ Encryption in transit

☐ Pseudonymization (replacing identifiers with codes)

☐ Role/Attribute Based Access Control (only authorized personnel)

☐ Secure storage (locked cabinets, protected servers, backups)

☐ Traceability (logging)

☐ Staff training on data protection

☐ Other:

Describe briefly:

1.6 Data Protection Impact Assessment (DPIA)

A DPIA may be required when processing is likely to result in high risk to individuals' rights and freedoms.

a) In your opinion, does this study involve any of the following?

☐ Systematic and extensive evaluation of personal aspects (e.g., profiling)

☐ Large-scale processing of special categories of data (e.g., biometric data of many participants)

☐ Systematic monitoring of participants

☐ Processing of data concerning vulnerable subjects (e.g., children)

☐ Use of new technologies that may pose risks

☐ None of the above

b) When two or more of the above conditions occur, a DPIA should be conducted. Based on your assessment, do you believe a DPIA should be conducted for this study?

☐ Yes ☐ No ☐ Uncertain

Please explain why you think a DPIA is or is not necessary.

B2. INFORMED CONSENT AND DATA SUBJECT RIGHTS

Note on the legal basis for data processing: In the EYE-TEACH project, all research activities involving human participants are experimental in nature. Participation is voluntary and requires informed (ethical) consent. When a person agrees to participate in a study, they are also asked to consent to the processing of their personal data. This is because research cannot be conducted without collecting and analyzing participant data. Therefore, in this project, the legal basis for processing personal data is the participant's consent (as defined by European General Data Protection Regulation). This means that:

– participants must be clearly informed about how their data will be collected, used, and protected;
– participants must explicitly agree to this data processing;
– participants can withdraw their consent at any time.
The following questions address how consent for data processing is obtained and how participants can exercise their rights over their personal data.

2.1 Consent for Data Processing

How is consent for data processing requested and obtained?

a) Is consent for data processing separate from consent to participate in research (section A6), or combined in a single form?

b) Is consent documented (e.g., signature, checkbox)?

c) Is information provided in a concise, transparent, intelligible and easily accessible form, using clear and plain language, in particular for any information addressed specifically to a child?

2.2 Right to Withdraw Consent and Data Erasure

Note: This question is linked to question 6.4 (Right to Withdraw from Research) of Section A. When a participant decides to withdraw from the study, they may also choose to withdraw their consent for data processing. However, these are two separate decisions:
– A participant may withdraw from the study but still allow the use of data collected up to that point;
– If a participant also withdraws consent for data processing, this normally results in erasure of their data, unless erasure would seriously compromise the research objectives.

a) How can participants withdraw their consent for data processing?

b) Is withdrawal of consent for data processing automatic when withdrawing from the study, or must it be requested separately?

c) Does withdrawal of consent for data processing result in erasure of their data?

☐ Yes – data will be erased upon withdrawal of consent

☐ No – the participant may withdraw from the study but consent to use of data already collected

d) If erasure is not possible, please explain why it would render impossible or seriously impair the research objectives.

2.3 Other Data Subject Rights

a) Participants have certain rights regarding their personal data. Describe how participants can exercise:

- Right of access (to know what data is held about them)

- Right to rectification (to correct inaccurate data)

- Right to erasure (where applicable, as described above)
- Right to restriction of processing

b) Who is the contact point for data subject requests?

B3. ARTIFICIAL INTELLIGENCE

AI INVOLVEMENT IN THE STUDY

3.1 Purpose and Type of AI Used

If AI tools are used, describe:

a) The specific purpose(s) for which AI is used (e.g., eye-tracking analysis, facial expression recognition, speech analysis, behavioral coding, predictive modeling, data classification, etc.).

b) What type of AI models, algorithms, or platforms are used (commercial, open-source, custom-developed).

3.2 Contribution to AI Development and Data Used

If the study contributes to AI system development:

a) How does the study contribute to the (pre)design, development and/or improvement of the AI-assisted ET-analytics pilot system?

b) The data collected in the study (see Section B1) are used for:

☐ Training AI models

☐ Validation/test of AI models/system

☐ Other:

AI ACT EXEMPTION

3.3 AI Act Applicability

Regarding the AI system involved in this study, which situation best applies?

☐ The AI system is developed and used for the sole purpose of scientific research, with no intention of placing it on the market or putting it into service for operational use (potential Art. 2(6) AI Act exemption)

☐ The AI system is intended for future market release or operational use, but is currently in research and development phase prior to being placed on the market or put into service (Art. 2(8) AI Act applies – note: testing in real world conditions is not covered by this exemption)

☐ Uncertain

3.4 Testing Environment

a) If testing involves participants, describe the testing environment:

☐ Laboratory with volunteers (specify whether adults or children):

☐ Real classroom with researchers present and controlled protocol

☐ Real classroom in normal operating conditions

b) In your opinion, would you consider this testing environment to be "real world conditions" (i.e., the actual context where the system would be used operationally)?

☐ Yes ☐ No ☐ Uncertain

Please explain your reasoning:

AI ACT RISK CLASSIFICATION

3.5 Inferences and Derived Data

a) What inferences or predictions does the AI system generate from participant data?

☐ Physical and mental states (pain, fatigue, cognitive load, attention, etc.)

☐ Emotional states (happiness, sadness, anger, surprise, disgust, embarrassment, excitement, shame, contempt, satisfaction, amusement, frustration, boredom, arousal, etc.)

☐ Learning-related inferences (comprehension level, learning difficulties, etc.)

☐ Other:

b) Could these inferences reveal sensitive information not explicitly collected (e.g., health status, cognitive disabilities, learning disorders)?

☐ Yes ☐ No

If yes, provide details:

3.6 Scope of AI Function

a) Could the AI system pose a significant risk of harm to the health, safety or fundamental rights of natural persons, or influence the outcome of decision-making processes?

☐ Yes ☐ No

b) If no, is the AI system intended:

☐ to perform a narrow procedural task within the overall evaluation process?

☐ to improve the result of a previously completed human activity?

☐ to detect decision-making patterns or deviations from prior decision-making patterns without replacing or influencing the previously completed human assessment, without proper human review?

☐ to replace or influence human assessment? If so, is there a subsequent human review process?

☐ to perform a preparatory task relevant to an assessment for other purposes? In so, specify what purposes.

Declarations and Signatures

By signing below, the Principal Investigator confirms that:

- The information provided in this protocol is accurate and complete
- Any significant changes to the protocol will be submitted for ethics review
- Adverse events will be reported promptly to the EYE-TEACH project coordinator

Principal Investigator

Name: _____

Signature: _____

Date: _____

Head of Department / Supervisor (if applicable)

Name: _____

Signature: _____

Date: _____

Attachments Checklist

Please attach the following documents as applicable:

- Information Sheet for Participants
- Informed Consent Form
- Parental/Guardian Consent Form (if minors involved)
- Assent Form for Minors (if applicable)
- Information Sheet and Consent on Data Processing
- Recruitment Materials (flyers, emails, social media posts)
- Questionnaires / Survey Instruments
- Interview Guides / Topic Lists
- Ethics Approval(s) by the University Ethics Committee(s)
- Data Processing Agreements (if third-party processors involved)
- A summary of key findings of DPIA (if applicable)
- Other:

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