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Ethics Management Plan - Initial

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Authors	Aïna Chalabaev (UGA), Laetitia Minniti (UGA), Alexa Comte (UGA)
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Executive Summary

This Ethics Management Plan outlines the measures implemented to ensure that the YEAH! project adheres to the highest ethical standards in compliance with European and national regulations. The protection of participants' rights, data security, and adherence to ethical research principles are at the core of our approach.

All participants, or their legal representatives, will provide informed consent before any data collection. Specific national regulations will be strictly followed to ensure compliance with local laws. Children and adolescents will provide assent, and their dissent will be respected. Measures are in place to prevent coercion and guarantee that participation remains entirely voluntary.

Personal data will be pseudonymized and securely stored, with access strictly limited to authorized personnel. All data transfers will comply with GDPR and relevant data protection frameworks. AI-assisted data analysis will follow strict bias mitigation strategies to prevent discrimination and stigmatization, ensuring fairness and representativity in the research process.

To safeguard participants' well-being, all potential risks will be clearly communicated, and psychological support mechanisms will be available. Behavior change counselors will be trained to monitor and respond to any signs of stress or discomfort. Specific measures will be implemented to prevent negative social dynamics, such as stigmatization or pressure related to health behaviors, reinforcing inclusivity and positive reinforcement throughout the study.

This plan ensures that all ethical considerations are proactively managed, protecting participants while maintaining the scientific integrity of the YEAH! project.

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Abbreviations

CA	Consortium Agreement
DMP	Data Management Plan
DPO	Data Protection Officer
EC	European Commission
EMP	Ethics Management Plan
FAIR	Findability, Accessibility, Interoperability, Reusability
GA	Grant Agreement
GDPR	General Data Protection Regulation
R&I	Research and Innovation
RCT	Randomized Controlled Trial
RIPP	Research Integrity Promotion Plan
RPO	Research Performing Organisation
SOP	Standard Operating Procedure
SOPs4RI	Standard Operating Procedures for Research Integrity
UGA	Université Grenoble Alpes
WP	Work Package

1. Introduction

1.1 Project Overview

Empowering children and adolescents to adopt healthy lifestyles while tackling health inequalities is crucial. Person-centred interventions have been developed to this end but face several challenges: they are often restricted to one specific actor of children's environment (teachers, parents, or peers) and rarely target several significant others simultaneously, they are often restricted to one specific behavior (e.g., physical activity) or life domain (e.g., school), their effectiveness may differ according to socio-economic or socio-spatial conditions, and they are rarely both largescale and personalised to individuals' needs. To address these challenges, and in line with the call, the ambition of YEAH! is to develop an innovative personalised person-centred digital intervention that: (1) promotes children (8-10 years) and adolescents' (14-16 years) social interactions with multiple actors of their environment, (2) targets multiple health behaviors (physical activity, sedentary behaviors, diet, sleep), (3) combines in a novel manner evidence-based knowledge of optimal intervention features (theory-driven approach), with co-creation with end-users and stakeholders (data-driven approach) to tailor the intervention to the local context and target group, and (4) relies on a state-of-the-art method of intervention development to rigorously measure and verify its impact, optimise its sustainable implementation in the community and its equity, and evaluate its cost-effectiveness. To do so, YEAH! will articulate interdisciplinary methods and concepts from psychology (health, social, developmental), public health, psychiatry, social marketing, geography, geomatics, environmental epidemiology, IT and computer sciences, statistics, physiology, and medicine, and on the participation of stakeholders (children and adolescents, parents, teachers, healthcare professionals, educators, local and national authorities).

These objectives raise ethical issues in relation (1) to the study of children and adolescents, which poses issues in terms of **free informed consent** to participate, (2) to the study of vulnerable and non-vulnerable populations, which poses issues in terms of **fair distribution** of benefits and burden of the YEAH! intervention, and (3) to the use of digital solutions to personalise the intervention, which poses issues in terms of **personal data protection**.

Furthermore, the YEAH! project must address additional ethical challenges related to the use of digital solutions. First, the integration of algorithms to personalize the intervention raises concerns about potential biases, requiring careful design and continuous monitoring to ensure fairness and equity across diverse populations. Second, the environmental impact of digital tools must be considered, particularly in terms of their carbon footprint and

sustainability. Finally, the randomized controlled trial (RCT) design used to evaluate the intervention necessitates careful attention to potential psychological impacts on participants.

1.2 Purpose of the Ethics Management Plan

The Ethics Management Plan (EMP) serves as a framework to ensure that all research activities within YEAH! adhere to the highest ethical standards and comply with relevant international, European, and national regulations. Given the project's focus on children, adolescents, and digital health interventions, a robust ethical framework is essential to safeguard participants' rights, well-being, and data privacy.

The main objectives of this EMP are to:

1. **Establish ethical guidelines, procedures, and protocols:** This plan defines the ethical principles and operational procedures that all project partners must follow, ensuring that research is conducted with integrity, fairness, and transparency.
2. **Conduct ethics assessments and audits:** Regular ethics reviews, audits, and compliance checks will be carried out to ensure alignment with relevant regulations and ethical standards. These assessments will help identify potential risks and implement mitigation strategies.
3. **Provide training and support on ethical best practices:** Training sessions will be provided to all project partners to enhance their understanding of ethical principles, informed consent procedures, data protection regulations, and responsible research practices.
4. **Address ethical concerns in a timely and transparent manner:** A structured mechanism will be in place to identify, report, and resolve any ethical issues that may arise during the project.
5. **Ensure accountability through documentation and reporting:** All ethical decisions, actions taken, and outcomes will be systematically documented. This ensures traceability and promotes transparency in the project's ethical management.

1.3 Scope of the Ethics Management Plan

The Ethics Management Plan (EMP) applies to all research activities within the YEAH! project, ensuring ethical compliance across study design, data collection, participants interactions, and dissemination of results.

It specifically addresses:

- **Human participant research** with a focus on ethical considerations related to children, adolescents, and vulnerable populations.
- **Informed consent procedures** ensuring voluntary, transparent, and age-appropriate participation.
- **Data protection and privacy** safeguarding personal data in compliance with General Data Protection Regulation (GDPR) and other relevant regulations.
- **Ethical risk management** providing mechanisms to identify, assess, and mitigate ethical risks throughout the project's lifecycle.

This plan serves as a guiding document for all partners, aligning the project's ethical commitments with international, European, and national regulations.

While the Ethics Management Plan (EMP) provides a comprehensive ethical framework for the YEAH! project, it **cannot anticipate every potential ethical challenge** that may arise due to the dynamic nature of research or specific local contexts. The plan will require an update at M32 in response to evolving regulations or unforeseen ethical issues.

2. Relevant International and EU Standards and Conventions

YEAH! complies with ethical principles and EU, international and national laws, to promote research integrity and excellence, in line with Horizon Europe Work Programme 2023-24. Ethics requirements are stipulated in Annex 5 of the **Grant Agreement (GA)**, under the Specific Rules, Ethics – **Article 14**, which serves as the primary reference for addressing ethical concerns related to the project. Additionally, the **Consortium Agreement (CA)**, in **Section 4: Responsibilities of Parties**, extends the provisions outlined in the GA to the Partners, who are committed to ensuring compliance with ethical standards throughout the project's duration.

The partners of the YEAH! project must carry out the action in full compliance with the highest standards of ethical principles and applicable legal frameworks, both within the EU and internationally. This includes adherence to the following regulations and guidelines.

2.1 Ethical Principles and Research Integrity

The partners are required to follow ethical principles, including the highest standards of research integrity, throughout the entire project. This is aligned with the **European Code of Conduct for Research Integrity**¹, which emphasizes the following core principles:

- **Reliability** in ensuring the quality of research reflected in the design, the methodology, the analysis and the use of resources
- **Honesty** in developing, undertaking, reviewing, reporting and communicating research in a transparent, fair and unbiased way
- **Respect** for colleagues, research participants, society, ecosystems, cultural heritage and the environment
- **Accountability** for the research from idea to publication, for its management and organisation, for training, supervision and mentoring, and for its wider impacts

It means that beneficiaries must ensure that persons carrying out research tasks follow the good research practices including ensuring, where possible, openness, reproducibility and traceability and refrain from the research integrity violations described in the Code.

The beneficiaries must also comply with the relevant data protection regulations, including:

- The **EU Charter of Fundamental Rights**
- The **European Convention for the Protection of Human Rights**
- **Fundamental Freedoms**, along with their supplementary protocols

2.2 International and National Law

In addition to EU regulations, beneficiaries are required to comply with applicable international and national laws, ensuring that all research activities respect the legal and ethical frameworks in place in the countries where the research is being conducted.

2.3 Ethics Committees and Data Protection Regulations

All Research and Innovation (R&I) activities within the YEAH! project will comply with the relevant local ethics committees, and **Regulation (EU) 2016/679 (General Data Protection Regulation - GDPR)**. The project, which processes personal information about identifiable human research subjects, is subject to the GDPR requirements, ensuring that personal data is handled with the highest standards of confidentiality and protection.

¹ European Code of Conduct for Research Integrity of ALLEA (All European Academies).

2.4 SOPs4RI guidelines

The **Standard Operating Procedures for Research Integrity** (SOPs4RI) provide a framework to help Research Performing Organisations (RPOs) cultivate research integrity and reduce detrimental practice. A freely accessible online **toolbox** offers Standard Operating Procedures (SOPs) and guidelines to support RPOs in establishing robust governance structures that promote a culture of research integrity.

At the core of these guidelines lies the **European Code of Conduct for Research Integrity**, which defines reliability, honesty, respect, and accountability as fundamental principles. To uphold these standards, RPOs are encouraged to implement a **Research Integrity Promotion Plan** (RIPP), ensuring alignment with both national and international regulations. While the RIPP is primarily designed for institutions such as universities, its principles offer valuable insights that we will integrate into the YEAH! project. Maintaining high ethical standards is essential, and we will draw upon key elements of the RIPP framework to strengthen our approach:

- **Research Environment:** A supportive and fair research culture must be cultivated by addressing hyper-competition, publication pressure, power imbalances, and conflicts. Policies for recruitment, assessment, and promotion must be transparent and responsible, actively promoting diversity and inclusion.
- **Research Integrity Training:** Adequate training in research integrity must be provided to researchers at all career stages by qualified trainers. Specific training and opportunities for exchanging experiences should be offered to staff handling research integrity issues and to those teaching research integrity courses.
- **Supervision and Mentoring:** Competent supervision and mentoring must be offered to researchers at all stages of their career development. The RIPP should specify procedures and criteria for qualifying as a supervisor or mentor and should include guidelines for supervision and mentoring of researchers at different career stages, with due attention to responsible research practices.
- **Research Ethics Structures:** Dedicated and adequately trained research ethics committees reflecting the character of research activities within the organisation. The RIPP should include procedures for ethics review relevant to the various research areas and disciplines within the organisation.
- **Data Practices and Management:** Guidance, training, and adequate infrastructures related to data management must be provided. Specific policies and procedures included in the RIPP must address concerns such as data protection, privacy, and Intellectual Property Rights, and ensure compliance with national and international

regulations such as the General Data Protection Regulation (GDPR). The organisation must provide adequate infrastructures for secure data collection, storage, retention, archiving, and sharing. Moreover, data management must be facilitated and curation procedures aligned with FAIR principles with a view to making data findable, accessible, interoperable, and reusable.

- **Declaration of interests:** Researchers should be enabled to provide transparent declarations of interests and ensure that conflicts of interests are handled adequately. Researchers must be supported by policies and procedures in the RIPP that specify the organisation's approach to declaring interests and handling conflicts of interests in relation to research conduct, funding, peer review, evaluation, assessment, promotions, and collaboration. The RIPP must outline the steps that the organisation takes to be transparent and clear about potential conflicts of interests.
- **Research Collaboration:** Policies and procedures should ensure that research collaboration can be done responsibly in situations that demand specific attention, when EU-based researchers collaborate with researchers from countries not covered by the GDPR and the European Code of Conduct for Research Integrity, or when RPOs collaborate across sectors.
- **Publication and Communication:** Expectations about procedures related to the publication and communication of research results should be specified. Specific policies and procedures to be included in the RIPP should address the use of preregistration, preprints, and online repositories, guidelines for the attribution of authorship, procedures for handling authorship disputes, the organisational approach to open access, FAIR (Findable, Accessible, Interoperable, Reusable) data curation, expectations about the use of reporting
- **Dealing with Breaches of Research Integrity:** Transparent procedures should be set up to receive, detect, handle, and sanction research integrity breaches. Procedures to ensure that researchers can consult research integrity officers or councilors in confidence should be part of the RIPP. Research integrity bodies and standardised procedures within the organisation should be established or drawn on national arrangements. The RIPP should also outline remedies following detection of breaches of research integrity, such as correction or retraction of papers, sanctioning of researchers who engaged in misconduct, and appropriate steps towards prevention in the future.

3. Ethical Concerns in YEAH! and Mitigation Strategies

3.1 Research with Children and Adolescents: Consent, Rights, and Protection

Ethical Concerns

The involvement of children and adolescents in the YEAH! intervention raises ethical concerns related to **informed consent**, particularly given the potential vulnerability of the participants (e.g., socio-economic and socio-environmental conditions). The challenges include ensuring that children and adolescents fully understand the nature of the study and its implications, and that their **participation is voluntary** without coercion.

Mitigation Strategies

To mitigate the ethical risks:

- The studies protocols will be submitted for approval to the relevant **ethics committees** of the participant's countries.
- In line with ICE GCP E6, participants will be given an **informed consent** form and information sheets that are
 - written in terms they can **fully understand**
 - describe the aims, methods and implications of the project, the nature of the participation and any benefits, risks or discomfort
 - state that participation is **voluntary** and that anyone has the **right to refuse** to participate and to **withdraw** their participation or data at any time without any consequences
 - state how **data** are collected and protected and whether they will be destroyed or reused afterwards
 - state the procedures implemented in the event of unexpected or incidental findings

We will ensure that participants do **not feel pressured** or coerced into giving consent. No children will be contacted directly. Parents or legally authorised representative will give their consent by signing and dating the informed consent form and information sheets and will be provided with a copy of these documents. We will ensure they have sufficient information to provide their consent on behalf and in the best interests of the children. We will obtain the assent of children and adolescents and respect any dissent.

In countries where specific national regulations apply, such as the Netherlands, we will strictly adhere to local legal requirements. For example, for adolescents aged from 12 to 15 years old in the Netherlands, informed consent must be provided by both parents with legal authority as well as the adolescent. Adolescents aged 16 years old or older will be treated as adults and will provide informed consent themselves, without requiring parental consent. In such cases, we will ensure that parental contact is only made with the explicit consent of the adolescent, in compliance with Dutch law.

3.2 Inclusion of Vulnerable and Non-Vulnerable Populations: Fairness and Equity

Ethical Concerns

The inclusion of both vulnerable and non-vulnerable children and adolescents in the YEAH! intervention raises ethical concerns about ensuring **fairness and equity**. Specifically, there is a risk that the benefits and burdens of the intervention could be distributed unevenly, potentially exacerbating existing disparities in health and well-being between vulnerable and non-vulnerable populations. This includes concerns about the **unintended consequences** on the health behaviors, well-being, and weight status of vulnerable groups, which may not be adequately addressed by the intervention.

Mitigation measures

- **Dark Logic Model of Change:** A "dark" logic model will be developed to identify potential negative consequences of the intervention. This model will examine how certain features of the intervention could inadvertently harm vulnerable groups, particularly regarding their health behaviors and well-being.
- **Stakeholder Involvement:** The knowledge gained from Work Package (WP) 1, combined with input from vulnerable populations, will inform the design of the intervention in WP2, ensuring that all groups benefit equally from the intervention and that harmful effects are minimized.
- **Continuous Monitoring:** The intervention will be monitored throughout its implementation to identify any emerging disparities in impact, enabling timely adjustments to ensure fairness and equity for all participants.

3.3 Personal Data Collection, Processing and Protection

Ethical Concerns

The use of digital solutions in YEAH! raises several concerns regarding the collection, processing, and protection of personal data, particularly given the sensitive nature of health-related information for children and adolescents.

Mitigation strategies

- **Processing of previously collected data:** YEAH! will conduct meta-analyses on previously published data and datasets. Data available from published studies and cohorts can be used without additional ethical approval.
- **Collection, processing and protection of personal data:** Non-clinical personal data including physical activity monitoring data will be collected in YEAH! studies. Data collection, processing and protection procedures will be submitted for approval to both local ethics committees and data protection agencies. Data transfer between the project's partners will be subject to Material Transfer Agreements when required. We will ensure optimal data protection at all times of the project and document our compliance to **GDPR** by following the recommended steps:
 1. Designation of a pilot (partners' DPO)
 2. Mapping of the processing of personal data
 3. Prioritisation of the actions to be taken to comply with the obligations, in view of the risks that processing poses to the rights and freedoms of the persons concerned
 4. Risk management by a data protection impact analysis
 5. Organization of internal processes which guarantee data protection at all times
 6. Documentation of compliance.

All collected data will be **pseudonymized**. Participants will be assigned a unique, random, encrypted pseudonymized number for all their data. As data acquisition will be repeated for the same participant, a correspondence table between the pseudonymized number and the participant's name will be established and will be destroyed at the end of the project, as well as personal contact data. Participants will exercise their rights of access, rectification, or destruction of their data until the end of the study. Each implementing country will be responsible for storing its own consent forms as part of its regulatory submission. However, since Université Grenoble Alpes (UGA) will manage the data across all implementing countries and collect them via Redcap, UGA will also archive a copy of the consent forms.

- **Compliance with DMP:** In addition to the GDPR compliance outlined above, the project will ensure adherence to the Data Management Plan (DMP), which is currently under production and will be submitted at M6. The DMP will outline further data handling procedures and guidelines for the entire duration of the project, ensuring that data privacy and security are maintained across all stages of research.

3.4 Addressing AI-Related Biases

Ethical Concerns

The project will apply machine learning algorithms (a type of AI) and state-of-the-art exposome statistical methods to identify determinants of health behaviors in children and adolescents. This raises several ethical concerns:

- **Discrimination and Stigmatisation biases:** AI models may introduce biases if the training data is not diverse, if data distribution is unbalanced, or if preprocessing methods are not carefully managed. This could lead to unfair or stigmatizing conclusions.
- **Lack of Transparency and Explainability:** AI-generated insights can be difficult to interpret, making it challenging for stakeholders to understand how decisions are made and to trust the results.
- **Fairness in Algorithmic Outcomes:** Without regular checks, AI models might produce results that disproportionately impact certain groups based on socioeconomic status, geography, or other demographic factors.
- **Ethical Use of AI-Generated Insights:** AI-driven findings, such as vulnerability maps, could be misused in policy decisions, potentially reinforcing existing inequalities rather than reducing them.

Mitigation strategies

- **Prevent potential discrimination and stigmatisation biases:** The datasets used will be representative samples of their underlying population and, in time, represent different parts of Europe by being located in the North, Center, and South of Europe. Moreover, because biases can be introduced during data collection, data cleaning, or preprocessing, YEAH! will use procedures for data validation, preprocessing, and normalisation across cohorts that minimise these biases, by ensuring that data from each cohort is treated consistently and that any imbalances in data distribution (e.g., between socioeconomic groups or geographical locations) are adjusted

accordingly. This will limit the likelihood of AI-assisted analysis being biased with regard to discrimination and stigmatisation.

- **Ensure fairness and equity in algorithmic outcomes:** YEAH! will implement fairness audits and develop algorithmic fairness metrics, by conducting regular checks on the outputs to identify disparities in predictions or recommendations across different subpopulations (e.g., by race, gender, or socioeconomic status), and will take appropriate actions to address any inequities detected in the analysis.
- **Prevent potential for discrimination in post-project decision-making:** YEAH! will establish guidelines for the ethical use of AI-generated insights to prevent the misuse of project's outcomes (e.g., the vulnerability maps created in WPI) for discriminatory practices (e.g., policy decisions that would disadvantage certain areas), by ensuring that the results are contextualised within broader socio-political and historical frameworks. YEAH! will also establish post-project monitoring mechanisms to oversee how the results are applied in policy-making or public health interventions.

3.5 Environmental Ethics: Carbon Footprint and Sustainability of Digital Tools

Ethical Concerns

The activities of the project could cause environmental damage related to the development of a mobile application and to the research activities themselves (e.g., carbon footprint related to travels).

Mitigation Strategies

The digital solution will be developed based on a **digital sobriety plan**, and purchases will be made only when they are crucial for the project implementation, with specific attention to their carbon footprint. Travels will also be limited by locating consortium meetings in places that are central and accessible for all partners (e.g., Brussels), and by regrouping at least one meeting with a conference most partners will attend.

3.6 Randomised Controlled Trial (RCT) Design and Psychological Impact

Ethical Concerns

The RCT design raises concerns about equity, as participants in the control group will not receive the intervention, which may lead to perceived unfairness in benefits. Additionally, there is a risk of stigmatisation or bullying, particularly related to the use of fitness trackers,

as this may draw unwanted attention to some children and adolescents. It is crucial that the digital tools and questionnaires are appropriately tailored to the target age groups, ensuring they are easy to understand, non-intrusive, and free from offensive content. Furthermore, the presentation of results must ensure pseudonymity, with data being reported at a group level to prevent identification of individual participants and avoid reinforcing stereotypes or negative perceptions of certain social groups.

Mitigation Strategies

- Participants in the RCT control arm will not benefit from the intervention but will be provided with fitness trackers to **self-monitor their health behaviors**, and participants from both arms will **keep the fitness tracker** after the end of the intervention.
- A key objective is to develop a co-created intervention effective in children and adolescents from various contexts, and to develop **positive relationships** between children and adolescents and their social environment, limiting the risk of harmful consequences (stigmatisation, bullying).
- Questionnaires will be **validated for the target age groups** with the aim to be easily understandable, avoid offensive content, and be not too long to complete. We will ensure high acceptability of the fitness tracker and digital solution and absence of offensive content.
- Results will be presented at the **group level** and will not be presented in a way that individual children and adolescents can be identified, nor that some social groups will experience stigmatisation.

4. Informed Consent and Participant Rights

4.1 Informed Consent Procedures

In line with ICE GCP E6, participants will be given an informed consent form and information sheets that are:

- written in terms they can **fully understand**
- describe the aims, methods and implications of the project, the nature of the participation and any benefits, risks or discomfort
- state that participation is **voluntary** and that anyone has the right to refuse to participate and to withdraw their participation or data at any time without any consequences

- state how **data** are collected and protected and whether they will be destroyed or reused afterwards
- state the **procedures** implemented in the event of unexpected or incidental findings

We will ensure that participants do not feel pressured or coerced into giving consent. No children will be contacted directly. Parents or legally authorised representative will give their consent by signing and dating the informed consent form and information sheets and will be provided with a copy of these documents. We will ensure they have sufficient information to provide their consent on behalf and in the best interests of the children. We will obtain the assent of children and adolescents and respect any dissent.

In countries where specific national regulations apply, such as the Netherlands, we will strictly adhere to local legal requirements. For example, for adolescents aged from 12 to 15 years old in the Netherlands, informed consent must be provided by both parents with legal authority as well as the adolescent. Adolescents aged 16 years old or older will be treated as adults and will provide informed consent themselves, without requiring parental consent. In such cases, we will ensure that parental contact is only made with the explicit consent of the adolescent, in compliance with Dutch law.

4.2 Documentation of Informed Consent

All consent documentation will be securely stored to ensure confidentiality and compliance with data protection regulations. Each implementing country will be responsible for storing its own paper consent forms as part of its regulatory submission. However, since UGA will manage the data across all implementing countries and collect them via Redcap, UGA will also archive a copy of the consent forms.

A scanned copy will be stored in each partner's secure storage device in access-restricted folders. The paper copies will be destroyed at the end of the project. Online consents will be stored on EUSurvey and subsequently transferred an access-restricted folder on each partner's secure storage device. The access will be granted only to partners of the consortium and will be password protected. Each partner has access only to its own data. Upon completion of the project, electronic copies of the consent forms will be securely archived for up to five years to meet EC requirements. To protect participant confidentiality, these copies will be stored in a sealed, encrypted file, accessible only under strictly controlled conditions.

Throughout the project, we will ensure full compliance with GDPR regulations, maintaining optimal data protection at all times. Participants will have the right to access, rectify, or request the deletion of their data until the end of the study.

5. Monitoring, Reporting, and Accountability

5.1 Role of the Ethics Committee

The **Ethics Committee** reviews and approves all YEAH! activities involving human subjects, sensitive data, or potential ethical implications. It will also oversee the implementation of mitigation strategies for any identified ethical risks, addressing any concerns or issues that arise during the course of the project in a timely and transparent manner.

5.2 Ethics Audits and Compliance Checks

Regular **ethics assessments and audits** will be conducted to ensure compliance with relevant regulations and ethical standards. These audits will evaluate the effectiveness of the mitigation strategies, verify adherence to ethical approvals, and ensure that all ethical practices and data protection measures are being followed throughout the project. The results of these audits will be documented, reviewed, and used to improve practices where necessary.

5.3 Documentation of Ethical Decisions, Actions, and Outcomes

All ethical decisions, actions taken, and outcomes will be documented and stored securely in an access-restricted area within the project's ShareDocs platform. This documentation will be accessible to authorized personnel, including members of the Ethics Committee, the Project Coordinator and the Project Manager, for auditing and accountability purposes. These records will be maintained to support transparency and provide a clear record of how ethical issues were handled throughout the project.

5.4 Updates and Revisions of the Ethics Management Plan

An official update of the EMP will be submitted to the European Commission at **M32** for approval.

The Ethics Management Plan (EMP) will also be updated when needed to ensure that it remains aligned with emerging ethical challenges, changes in legislation, or project developments. These updates will be documented clearly and communicated to all project partners to ensure a shared understanding and smooth implementation.

6. Ethical Breaches and Non-Compliance

In the event of an ethical breach or non-compliance, the following steps will be taken:

- **Reporting:** Any breach of ethical standards or failure to comply with project protocols must be reported to the Ethics Committee and the Project Coordinator. Partners will have access to a confidential reporting mechanism.
- **Investigation:** The Ethics Committee will conduct an investigation of the reported breach or non-compliance issue, considering the nature, scope, and potential impact on the project.
- **Corrective Actions:** If a breach is confirmed, corrective actions will be proposed and implemented promptly. These may include re-training, changes to procedures, or other remedial measures to prevent further non-compliance.
- **Documentation and Transparency:** All actions taken in response to an ethical breach or non-compliance will be documented and included in regular reports for accountability purposes. These records will be stored securely in ShareDocs, the project's document-sharing platform, within a restricted-access folder that is only accessible to members of the Ethics Committee, the Project Coordinator and the Project Manager.

7. Training and Support on Ethical Best Practices and Procedures

This section outlines the plan for ensuring all project partners are equipped with the necessary knowledge, tools, and resources to implement ethical best practices throughout the project.

7.1 Training Program Overview

A comprehensive **training program** will be developed and delivered to all project partners to ensure a shared understanding of ethical principles, regulations, and responsibilities. This will include:

- **Initial Training:** A mandatory session at the start of the project, covering key ethical issues such as informed consent, data protection, and the handling of sensitive information.

- **Ongoing Training:** Regular follow-up sessions to address emerging ethical concerns, reinforce best practices, and update partners on any regulatory changes. These sessions may be delivered online, in-person, or through a hybrid model to ensure maximum accessibility.

7.2 Key Training Areas

The training will focus on the following critical ethical areas:

- **Informed Consent Procedures:** Ensuring all partners understand the importance of obtaining informed consent, and how to carry out this process in a manner that is clear, transparent, and respectful of participants' rights.
- **Data Privacy and Protection:** Training on data protection laws (GDPR, etc.), secure data handling, pseudonymization, and how to maintain confidentiality throughout the project.
- **Ethical Decision-Making:** Equipping partners with decision-making tools to navigate ethical dilemmas, including conflict resolution, handling unexpected findings, and protecting vulnerable groups.

7.3 Support Mechanisms

Ethics Management Plan (EMP)

This EMP serves as a comprehensive framework, providing all partners with ethical guidelines, procedures, and protocols to ensure consistent compliance with ethical standards. It outlines steps for handling ethical issues, conducting ethics assessments, and documenting decisions.

Ethics Committee

The project's Ethics Committee will play a key role in supporting partners. The committee will be responsible for reviewing and approving all YEAH! activities that involve human subjects, sensitive data, or have potential ethical implications. The committee's oversight will ensure that the project complies with ethical standards and regulations at every stage.