Recommendations on the Ethical dimension of the E-OILé project

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HOLOSS

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1. Summary

The E-OILé project is an initiative committed to ensuring that all research and innovation activities are conducted in accordance with the highest ethical standards and in full compliance with the current applicable European legislation. To support this commitment, HOLOSS has established a comprehensive and transparent ethical monitoring framework designed to identify, assess, and address ethical considerations throughout the project lifecycle.

Accordingly, in its role as Ethics Mentor, HOLOSS provides continuous guidance to project partners on ethical requirements, supports the implementation of ethical principles across all project activities, and monitors compliance with relevant ethical standards. This role also involves identifying potential ethical risks at an early stage and ensuring that appropriate mitigation measures are implemented where necessary. Hence, key areas of oversight include research integrity, data protection and privacy, the involvement of human participants, environmental, health and safety considerations, the ethical use of artificial intelligence, inclusiveness, and other relevant ethical dimensions.

Giving this context, as part of the project's periodic ethical monitoring process, partners are invited to reflect on the ethical implications of the activities associated with each project deliverable, document any relevant ethical considerations, and report the measures adopted to prevent or mitigate potential risks. As a result, this proactive and collaborative approach aims to promote responsible research and innovation, strengthens transparency and accountability, and ensures that the E-OILé project's outcomes are developed in alignment with European ethical values, principles, and regulatory requirements.

Lastly, the present recommendations list is intended to guide and remind all project partners of their ethical responsibilities throughout the implementation and deployment of the E-OILé project. Hence, they serve as a practical reference to support the identification, assessment, and appropriate management of ethical considerations that may arise during project activities, while promoting compliance with the current applicable European legislation and the principles of responsible research and innovation.

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2. Ethical monitoring framework within the E-OILé project

The ethical monitoring framework of the E-OILé project aims to ensure that project activities comply with the ethical requirements established by the European Commission for research and innovation projects. As research activities progress, new ethical considerations may emerge, requiring continuous assessment and appropriate mitigation measures. The ethical monitoring process is based on relevant European guidance, including the Horizon Europe Ethics Framework, the Ethics Self-Assessment approach, the principles of Responsible Research and Innovation (RRI), and internationally recognised ethical standards.

Following the amendment requested by the Project Officer, the E-OILé project incorporated a dedicated ethics dimension within Task 8.2, led by GAIKER, while the implementation and coordination of the ethics-related activities remain under the responsibility of HOLOSS. Given its exclusive focus on ethics, the adopted methodology is centred on the ethical areas identified in the Horizon Europe Ethics Self-Assessment and aims to provide continuous support to partners throughout the project lifecycle.

The review and monitoring activities focus on key areas that may present ethical considerations including:

- **Human participants and informed consent**, ensuring respect for autonomy, dignity, and fundamental rights.
- **Personal data protection and privacy**, ensuring lawful, transparent, and secure data management.
- **Animal research and human cells/tissues**, ensuring compliance with relevant ethical approvals and regulatory requirements.
- **Environmental, health, and safety considerations**, ensuring prevention and mitigation of potential risks.
- **Artificial intelligence and emerging technologies**, promoting transparency, fairness, accountability, and responsible use.
- **Dual-use and potential misuse concerns**, ensuring responsible management of research outputs.
- **Research integrity**, promoting honesty, transparency, and accountability in scientific activities.
- **Gender equality, diversity, and inclusion,** ensuring equal opportunities and preventing discrimination.

To date, the ethics monitoring methodology has combined awareness-raising, guidance, and continuous monitoring activities. Accordingly, a set of ethics surveys have been already introduced as a continuous monitoring mechanism, across the consortium to assess partners' awareness, existing practices, and understanding of the ethical issues relevant to the project. As a result, these questionnaires provide an

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opportunity to assess the ethical aspects associated with the work performed, identify emerging ethical issues, and implement appropriate mitigation measures where necessary. In parallel, the findings also served to inform the organisation of an Ethics in Research and Innovation seminar, which aimed to introduce the main ethical topics applicable to E-OILé, reinforced partners' understanding of their ethical obligations under Horizon Europe, and promoted responsible research and innovation practices across the consortium.

Building on these activities, a set of practical ethical recommendations has been developed and will be periodically updated to support partners in maintaining compliance with applicable ethical and legal requirements while strengthening ethics awareness throughout the project. Accordingly, the ethical review process is therefore not intended solely as a compliance exercise but as a continuous support mechanism to help partners identify challenges, address ethical concerns proactively, and ensure that E-OILé contributes to responsible, trustworthy, and impactful research and innovation.

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3. Recommendations

3.1. Human Participants and Informed Consent

Researchers should:

- Ensure that any involvement of human participants respects **human dignity**, **autonomy**, **fundamental rights**, and **personal integrity**.
- Ensure that participation is based on free, informed, and explicit consent, obtained before any research activity begins.
- Provide participants with clear information regarding:
  - the purpose and objectives of the research;
  - procedures and methods involved;
  - potential risks and benefits;
  - use, storage, and sharing of collected information;
  - their right to withdraw participation at any time.
- Implement additional safeguards when research involves vulnerable individuals or groups.
- Ensure that appropriate ethics approvals are obtained before conducting activities involving human participants.
- Maintain appropriate documentation demonstrating compliance with ethical requirements.

3.2. Personal data protection

Researchers should:

- Ensure that all processing of personal data complies with applicable legislation, including the **General Data Protection Regulation (EU) 2016/679 (GDPR)** where applicable.
- Apply the principles of:
  - data minimisation;
  - purpose limitation;
  - Transparency;
  - Confidentiality;
  - accountability.
- Clearly define:
  - what personal data are collected;
  - the purpose of processing;
  - who has access to the data;
  - how long data will be retained.
- Apply appropriate technical and organisational security measures.
- Use anonymisation or pseudonymisation techniques whenever possible.
- Ensure that participants are informed about their data rights.

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- Establish procedures for secure storage, transfer, sharing, and deletion of personal data.

3.3. Human Cells and Tissues

Researchers should:

- Ensure that human cells and tissues are collected, processed, stored, transferred, and used according to applicable EU and national legislation.
- Ensure appropriate informed consent and ethical approval procedures are followed.
- Guarantee traceability, confidentiality, and secure management of biological materials.
- Ensure that secondary use or transfer of biological materials complies with the conditions under which they were originally collected.
- Follow relevant quality and safety requirements, including those established under **Directive 2004/23/EC on human tissues and cells**, where applicable.

3.4. Animal research

Researchers should:

- Avoid the use of animals whenever scientifically valid alternatives exist.
- Apply the **3Rs principles**:
  - **Replacement:** use alternative methods instead of animals whenever possible;
  - **Reduction:** minimise the number of animals required;
  - **Refinement:** minimise pain, suffering, distress, and lasting harm.
- Ensure that animal experiments are conducted only after obtaining the necessary ethical approvals and authorisations.
- Ensure compliance with applicable legislation, including **Directive 2010/63/EU on the protection of animals used for scientific purposes**.
- Ensure that personnel involved in animal research have appropriate training and competence.
- Monitor animal welfare throughout the research process.

3.5. Artificial Intelligence

Researchers should:

- Ensure that AI systems are developed and/or used responsibly and in compliance with applicable legal requirements, including the **EU Artificial Intelligence Act (Regulation (EU) 2024/1689), where applicable**.
- Assess and mitigate risks related to:

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- bias;
- discrimination;
- lack of transparency;
- unreliable outputs.

- Ensure appropriate human oversight of AI-supported processes.
- Ensure transparency regarding:
  - the use of AI systems;
  - their limitations;
  - their intended purpose.
- Ensure that datasets used for AI are:
  - relevant;
  - representative;
  - appropriately managed;
  - legally obtained.
- Consider environmental impacts associated with AI development and use.

3.6. Environmental and Health risks

Researchers should:

- Identify and assess potential risks to:
  - human health;
  - worker safety;
  - the environment;
  - ecosystems.
- Implement preventive and mitigation measures before and during research activities.
- Ensure safe handling, storage, transport, and disposal of hazardous materials.
- Comply with applicable occupational health and safety and environmental regulations, including **Directive 89/391/EEC (the Occupational Safety and Health Framework Directive),** relevant national legislation, and any sector-specific regulatory requirements.
- Where applicable, implement environmental and occupational health and safety management practices consistent with internationally recognised standards, such as **ISO 14001 (Environmental Management Systems) and ISO 45001 (Occupational Health and Safety Management Systems).**
- Consider sustainability impacts, including:
  - resource consumption;
  - waste generation;
  - environmental footprint.
- Promote the efficient use of resources and apply the principles of pollution prevention and environmental protection throughout the research lifecycle.

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- Apply precautionary approaches when activities may generate uncertain but potentially significant risks, in line with the precautionary principle reflected in **Article 191 of the Treaty on the Functioning of the European Union (TFEU)**.

3.7. Non-EU countries

Researchers should:

- Ensure that any research activities conducted in, or involving partners, participants, data, biological materials, or resources from **non-EU countries** comply with **Regulation (EU) 2021/695 (Horizon Europe)**, applicable EU legislation, the national legislation of the country concerned, and relevant international conventions.
- Ensure that research carried out in non-EU countries adheres to **ethical standards equivalent to those required within the European Union**, respecting fundamental rights, human dignity, research integrity, and participant welfare.
- Obtain all necessary ethical approvals, permits, authorisations, and regulatory clearances required by both the EU and the country in which the research is conducted.
- Ensure that the transfer of personal data, biological materials, or research outputs outside the EU complies with applicable legal requirements, including the **General Data Protection Regulation (Regulation (EU) 2016/679)** where relevant.
- Respect local customs, cultural values, and community practices while ensuring that these do not compromise internationally recognised ethical principles or fundamental human rights.
- Assess and continuously monitor any ethical, legal, or security risks associated with international collaborations and implement appropriate mitigation measures where necessary.

3.8. Dual-use Concerns and Potential misuse of Research Results

Researchers should:

- Assess whether project outputs, technologies, materials, or knowledge could be misused for harmful purposes.
- Identify possible unintended consequences or applications beyond the intended objectives.
- Consider risks related to:
  - human safety;
  - environmental harm;
  - Security;
  - Misuse of technological developments.
- Implement appropriate safeguards to minimise misuse risks.
- Balance responsible dissemination of results with the need to prevent harmful exploitation.
- Ensure that activities remain focused on peaceful and civil applications where applicable.

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3.9. Research Integrity

Researchers should:

- Conduct research according to principles of:
  - Honesty;
  - Reliability;
  - Transparency;
  - Accountability.
- Ensure accurate collection, management, analysis, and reporting of research data.
- Avoid:
  - Fabrication;
  - Falsification;
  - Plagiarism;
  - Inappropriate manipulation of results.
- Maintain appropriate documentation and traceability of research activities.
- Ensure responsible authorship and recognition of contributions.
- Follow recognised standards such as the **European Code of Conduct for Research Integrity (ALLEA)**.

3.10. Gender Equality and Non-discrimination

Researchers should:

- Promote equality, diversity, and inclusion throughout all project activities.
- Ensure that **no discrimination occurs based on characteristics** such as:
  - gender;
  - gender identity;
  - age;
  - disability;
  - ethnicity;
  - nationality;
  - religion;
  - sexual orientation;
  - socioeconomic background.
- Consider sex and gender dimensions where relevant in:
  - research design;
  - methodologies;
  - data analysis;
  - research outcomes.

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- Ensure inclusive participation and equal opportunities within research teams.
- Maintain a working environment free from harassment and discrimination.
- Consider whether research outputs may disproportionately affect specific groups.

3.11. Guidelines for Gender-Inclusive Communication

- **Publish Responsibly:**
  - Use inclusive, gender-sensitive, and accessible language in all publications and dissemination materials.
  - Represent individuals and communities accurately, avoiding stereotypes, assumptions, or discriminatory terminology.
- **Communicate Responsibly:**
  - Ensure that publications, presentations, and outreach materials use respectful, inclusive, and unbiased language.
  - Present research findings accurately and transparently, avoiding sensationalism, overgeneralisation, or language that may stigmatise individuals or groups.
- **Reach Diverse Audiences:**
  - Use clear and accessible language that can be understood by diverse audiences.
  - Ensure visuals, examples, and communication materials reflect diversity and promote inclusion.
- **Promote Inclusive Publications:**
  - Use respectful and inclusive language that reflects the diversity of individuals and communities.
  - Review publications for biased, exclusionary, or stereotypical language before dissemination.

3.12. General Recommendations for Partners

Consortium partners are invited to continuously monitor ethical aspects throughout the project lifecycle, identify emerging ethical risks, maintain appropriate documentation, and implement mitigation measures whenever necessary. All activities should comply with applicable EU legislation, ethical standards, and institutional procedures. In case of any ethical doubts, concerns, or issues arising during project activities, partners are free to contact the responsible Ethics Mentor to seek advice and ensure that appropriate follow-up measures are identified and implemented in a timely manner.

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