

Independent Ethics Advisory Board Report # 1

e-QuoL Consortium

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e·QüoL

Equality · Quality of Life · Survivorship



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REPORT

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1. Introduction - Composition of the Independent Ethics Advisory Board

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This report provides the Independent Ethics Advisory Board (IEAB) review on the ethical dimensions of the e-QuoL project during the first reporting period (M1-M16). It evaluates ethical compliance, data protection, survivors' engagement, inclusiveness, and safeguarding principles across the project's activities.

2. Documents reviewed

To support the preparation of this report, the IEAB reviewed all relevant project deliverables submitted in 2024, with a particular focus on research protocols involving human participants — including surveys, co-creation workshops, and the clinical study framework. In addition, the annual ethical reflection report produced by the leaders of Work Package 6 was considered as a complementary element supporting ethical awareness across the project.

3. Ethical Issues Identified

Several ethical concerns have been identified:

- **Equity and access:** Disparities in access to digital tools across different European regions, particularly in non-EU countries

- **Informed consent for digital passport:** there are existing concerns about the extent to which survivors fully understand the implications outlined in consent forms, particularly about the use for long-term follow-up care. This is especially relevant for individuals in transitional developmental phases.
- **Data Privacy and Protection (GDPR Compliance):** Risk related to handling of sensitive personal health data, including the storage, access, and transfer of these data, particularly across international borders.
- **Vulnerable populations of childhood, adolescent and young adult cancer survivors (CAYACs):** It is essential to ensure that digital passport supports – rather than compromise – the psychosocial well-being, confidentiality, and autonomy of survivors throughout their continuum of care.

The table below illustrates identified ethical concerns, their relevance to project activities, and affected work packages.

Ethical concerns	Relevance to project activities	Affected work packages
Equity and access	May result in unequal benefits for survivors, thereby compromising fairness and inclusivity.	WP1, WP5, WP6
Informed consent	Impacts survivors’ autonomy and their ability to make informed decisions regarding the use of a digital passport.	WP2, WP4, WP6
GDPR compliance	Needs harmonization across partners; potential compliance risks	WP3, WP4, WP6
Vulnerable population of CAYACs	Ensures that a digital passport is safe and respectful to this vulnerable group.	WP2, WP5, WP6

4. Board Recommendations

EAB provides the following recommendations, prioritized by their level of importance:

- **Improve Informed consent procedures for digital tools – Mandatory**

Informed consent materials should be adapted to ensure clarity and accessibility for CAYACs using a digital passport, with particular emphasis on data usage, privacy, and their rights in digital settings.

- **Ensure equity in access to digital tools – Strongly recommended**

It is recommended that an accessibility and equity framework be established and enforced to ensure that a digital passport is universally accessible to all CAYACs, regardless of geographic region or socio-economic status, thereby promoting fair outcomes and preventing exclusion. To support the buy-in and commitment of each country's health service, it is important to consider a strategic approach. It could be proposed to establish a framework presenting the different steps to be disseminated in order to achieve widespread and equal implementation of LTFU digital platform across Europe.

- **Engage vulnerable populations groups – Strongly recommended**

It is recommended that CAYACs are associated with the initial design and be then actively engaged in the evaluation of the digital tools, to ensure their unique needs, preferences, and vulnerabilities are appropriately considered and addressed.

- **Conduct a Comprehensive GDPR Audit – Strongly recommended**

It is recommended that a comprehensive audit be performed across all consortium partners to assess current data protection practices and ensure full compliance with GDPR.

- **Design and implement an Ethics training program - Optional**

While not immediately required, ongoing ethics training for all project personnel could help embed a culture of ethical awareness within the e-QuoL project team, focusing on ethical principles, data protection, and equity in the delivery of digital tools.

5. Overall Ethical Evaluation of the Project

IEAB has reviewed the current ethical practices, documents, and implementation status across the e-QuoL project, focusing on adherence to ethical guidelines, legal frameworks, and consistency with fundamental ethical principles.

Overall, the project demonstrates a strong commitment to ethical conduct, with dedicated tasks (6.1 and 6.2) addressing ethics monitoring and reflection. Main ethical issues are clearly recognized in project planning, and are regularly implemented.

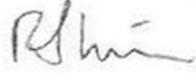
Equity considerations are acknowledged. However, there is a need for continuous efforts to ensure the consistent application of practical frameworks across different European regions. The timely implementation of ethical mechanisms will ensure full compliance and foster trust among participants. As an European group of researchers, it is important to reiterate that cultural diversity among the different countries members of the project are at our concern and considered when defining strategic approach of the project.

6. Conclusion

The e-QuoL project is progressing well in addressing ethical considerations. IEAB will continue to maintain its role in guidance and support, ensuring that all ethical principles are consistently applied.

7. Signatures

Include names, signatures, and dates for all EAB members.

Names	Dates	Signature
Roderick Skinner	May 15 th , 2025	
Louis S. Constine	May 25 th , 2025	
Michele Favreau	May 20 th , 2025	
Laura Beek	May 22 nd , 2025	

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