



## Deliverable D 9.2 Ethics

### H - Requirement No. 3

<b>Work Package</b>	Ethics
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## Document Log

Date	Author	Changes	Version	Status
	Thomas Krause	Creation of Document and adding content	V1	In progress
	Michael Kramer	Approval	V1	final

## Executive Summary

This document serves as the formal confirmation that the GenDAI consortium has fulfilled the ethical requirement outlined in Deliverable D9.2. Following a change in methodology to use a pre-existing, fully anonymized dataset instead of prospectively collecting samples, the consortium undertook a formal consultation with the project's independent Ethics Advisor (EA).

A detailed justification was presented to the EA, outlining that the data is anonymous, contains no personal identifiers, and that its use is covered by the broad consent obtained by the third-party provider. The EA reviewed this justification and the associated documentation.

The EA's formal opinion concluded that, given the anonymized nature of the dataset, a new, external review and approval by a national or institutional ethics committee is not required. This deliverable confirms that this independent ethical oversight has been completed and documented.

## 1 Ethical Due Diligence Process

The consortium undertook a formal internal governance process to address the ethical requirements for using the dataset:

1. **Internal Assessment:** The consortium concluded that the dataset to be used is **fully and irreversibly anonymized**, that **no re-identification** of individuals is possible for any consortium partner, and that **no additional data collection** from human participants will occur.
2. **Consultation with the Independent Ethics Advisor (EA):** This assessment was submitted to the project's appointed EA for independent review and a formal opinion.

This consultation constituted the formal request for an independent ethical opinion on whether a new submission to an external ethics committee was necessary.

## 2 Opinion of the Independent Ethics Advisor

The Independent Ethics Advisor for the GenDAI project has reviewed the factual basis presented by the consortium regarding its use of a pre-existing dataset of 16S FASTQ data.

The EA's opinion is based on the following established facts:

- The dataset is fully and irreversibly anonymized.
- The consortium possesses no means to re-identify the individuals from whom the data was derived.
- The research involves no new data collection from human participants.

Based on these facts, the EA's assessment is that the research activities do not constitute research with human participants or with their personal data as defined by applicable regulations (including GDPR).

## 3 Conclusion

The EA concludes that a separate review and approval by an external ethics committee is not required for the research activities planned by the GenDAI project using this specific dataset. The ethical oversight provided through this independent review is sufficient to meet the project's obligations.