SEMPRE-BIO

D7.8 Research Ethics and Data Protection Monitoring Report v1

SEcuring doMestic PRoduction of cost-Effective BIOmethane

CETAQUA
WATER TECHNOLOGY CENTRE

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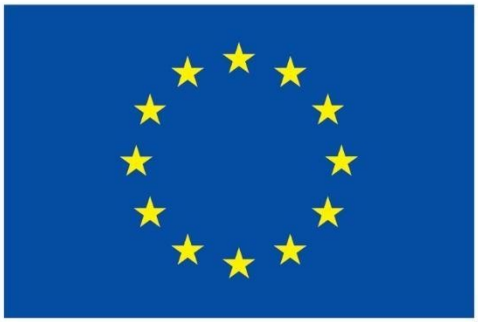
DISCLAIMER



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Content

Acronym Glossary

GDPR: General Data Protection Regulation	**GA:** Grant Agreement

Consortium partners

	Participant organisation name	Acronym
1	CETAQUA	CET
2	AIGUES DE BARCELONA	AB
3	CRYO INOX	CRYO
4	DEUTSCHES BIOMASSEFORSCHUNGSZENTRUM GEMEINNÜTZIGE	DBFZ
5	DANMARKS TEKNISKE UNIVERSITET	DTU
6	INVENIAM GROUP	INV
7	PROPULS	PROPULS
8	SINTEF	SINTEF
9	TERRAWATT	TERRA
10	TRANSPORTS METROPOLITANS DE BARCELONA	TMB
11	UNIVERSITEIT GENT	UGE
12	UNIVERSITAT DE VIC	UVIC
13	BIOGAS-E	BIOGAS-E
14	INNOLAB	INNOLAB
15	NATURGY	NAT
16	NV De Zwanebloem	MASS

1. Introduction

The deliverable D7.8 - Research Ethics and Data Protection Monitoring Report v1 defines the ethical framework and guidelines for conducting research activities within the SEMPRE-BIO project. This report aims to ensure that all research undertaken adheres to the highest ethical standards and complies with relevant legislation, particularly the General Data Protection Regulation (GDPR) 2016/679/EC on data protection and privacy. The document serves as a reference guide for researchers, outlining best practices and procedures to uphold ethical principles during the execution of their work. It provides a comprehensive overview of the legal and ethical foundations underpinning research conduct within the Horizon Europe framework.

This initial report lays the groundwork for ongoing ethical monitoring and data protection within the SEMPRE-BIO project. Subsequent updates on the ethical monitoring process will be provided at the project's endpoint (M42).

2. Research Ethics

The Sempre-Sio consortium recognizes the ethical implications associated with the proposed research and adheres to the ethical rules and standards established by the Horizon Europe Program, as well as those delineated in "Article 14 – Ethics and Values." Ethical considerations, societal impacts, and data protection measures are vital elements of this project.

Ethical considerations are an integral component of all research activities supported by the European Union, and adherence to ethical standards is crucial for achieving research excellence. Every project conducted under the Horizon Europe program must conform to ethical principles and pertinent national, EU, and international legislation. Moreover, the European Commission actively encourages the adoption of the highest levels of research integrity throughout Europe.

The Sempre-Bio consortium recognizes the importance of ethical considerations and is committed to upholding the highest ethical standards throughout the research project. This includes ensuring compliance with relevant ethical principles, legislation, and guidelines to maintain research excellence and integrity.

2.1. Rules for Carrying Out the Action

2.1.1. Article 14 – Ethics & Values

The Sempre-Bio beneficiaries must carry out the action in compliance with the Ethics requirements, as outlined in Article 14 of Annex 5, Section 2 - Rules for carrying out the action, in the Grant Agreement (GA).

According to the Grant Agreement of the Sempre-Bio project, in the section regarding Ethics and research integrity, the following paragraphs are relevant:

The beneficiaries must carry out the action in compliance with ethical principles (including the highest standards of research integrity) and the applicable EU, international and national law, including the EU Charter of Fundamental Rights and the European Convention for the Protection of Human Rights and Fundamental Freedoms and its Supplementary Protocols.

The beneficiaries must pay particular attention to the principle of proportionality, the right to privacy, the right to the protection of personal data, the right to the physical and mental integrity of persons, the right to non-discrimination, the need to ensure protection of the environment and high levels of human health protection.

In addition, the beneficiaries must respect the fundamental principle of research integrity – as set out in the European Code of Conduct for Research Integrity[1].

This implies compliance with the following 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.*

[1] The European Code of Conduct for Research Integrity serves as a framework for self-regulation across all scientific disciplines and research settings, with the 2023 Revised Edition updated to remain fit for purpose and relevant to all disciplines, emerging areas of research, and new research practices. Recognized by the European Commission as the primary standard for upholding research integrity across all research projects funded by the EU. Also, serves as a model for national and institutional codes of conduct, funding guidelines, training initiatives, and discipline-specific standards.

- *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.*

And 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.

Activities raising ethical issues must comply with the additional requirements formulated by the ethics panels (including after checks, reviews or audits; see Article 25 in the GA).

Before starting an action task raising ethical issues, the beneficiaries must have obtained all approvals or other mandatory documents needed for implementing the task, notably from any (national or local) ethics committee or other bodies such as data protection authorities.

The documents must be kept on file and be submitted upon request by the coordinator to the granting authority.

2.1.2. Ethics Guidelines

Horizon Europe has introduced an Ethics Procedure that includes Ethics processes before grant-signature and Ethics in the management of the grant.

a) Ethics processes before grant-signature

The Ethics Review Procedure should be conducted before the start of the project. The ethics process starts with an examination of the proposal, with particular attention paid to the ethics table and ethics self-assessment. For Horizon Europe programs, proposals may need to undergo an ethics review before selection. If one or more ethics issues are identified, they will be subject to ethics requirements that must be addressed immediately or implemented during the grant period. In the latter case, these requirements will be included as deliverables in Annex 1. As a result, the Sempre-Bio project conducted a preliminary evaluation using the Ethics Issue Table from Section 4 of the GA. This prior review did not identify any ethical issues, as stated in the GA table. However, if any ethics issues apply, the project should complete the ethics self-assessment[2].

- **Ethics self-assessment**

It covers common ethics issues that may arise in EU projects and provides advice on addressing them. Applicants must complete an ethics self-assessment if their proposal raises any of the listed ethics issues. This should describe the issues, how they will be addressed to ensure compliance, and provide any relevant documentation.

The ethics self-assessment becomes part of the GA (in Annex 1, as description of the action, ethics requirements, etc.) and may thus give rise to binding obligations that may later on be checked through ethics checks, reviews or audits, so the time invested in it is important. It helps ensure compliance with applicable international, EU and national law, allows easier processing, contributes to responsible implementation, and facilitates publication of results.

Ethics issues can arise in many areas beyond just medical research, such as research protocols in social sciences, ethnography, psychology, environmental studies, security research, etc. Applicants should think about ethics from the design phase and protect research subjects and personal data.

Applicants should first seek ethics advice from experts at their own institution, such as ethics committees, compliance managers, data protection officers, etc. as they can provide guidance specific to the applicant's situation and legal environment.

[2] How to complete your ethics self-assessment

b) Ethics in the management of the grant

As a simple administrative measure, it is important for each Beneficiary to maintain accurate records of all documentation pertaining to the ethics of the grant. As signatory to the GA, the coordinator is responsible for promptly providing copies to the European Commission upon request. Evidently, this documentation must exhibit coherence: for instance, it should be verifiable that informational materials and consent forms were obtained before the commencement of any experimental work.

Given the extended duration of the projects, it is common for new ethical considerations to emerge as the research takes unanticipated directions. For example, after three years of research, a new scenario approach that was not foreseen in the initial proposal could arise. It is essential to remain vigilant for such possibilities and promptly report significant new ethical issues to the European Commission. This can be done by contacting the Project Officer and by including the issue in a formal request for amendment of the technical description. In the case of substantial breach of ethical principles, research integrity, or relevant legislation an ethics audit can be undertaken. These ethics checks and audits can result in an amendment of the grant agreement. The aim of the Ethics Checks, Reviews and Audits conducted during the project is to ascertain that expected standards are met and that risks to research subjects and researchers are minimised.

- **Checks**

The granting authority can check the proper implementation of the action and compliance with the Agreement obligations during or after the action, including assessing costs, contributions, deliverables, and reports. This first phase aims to identify proposals that require ethical approval at the national level and identifies the proposals that require a full Ethics Review due to the ethical issues they raise.

- **Reviews**

After the check, the European Commission may require a full Ethics Review. An expert panel assesses compliance with ethical standards, relevant laws, and the applicants' awareness of ethical and social impacts.

The granting authority can conduct project reviews during or after implementation to verify compliance with the Agreement obligations. These may involve independent experts and require the beneficiary to provide information, attend meetings, and allow site visits. A project review report is issued, and the beneficiary has 30 days to provide observations. Reviews are conducted in the Agreement language.

- **Audits**

During the Checks or Reviews, experts identify projects requiring follow-up or audits. These procedures assist beneficiaries in addressing ethical issues and taking corrective measures during the research project.

The granting authority can conduct audits to verify compliance with the Agreement, using internal auditors, centralized services, or external firms. Beneficiaries must cooperate, provide requested information (including accounts and personal data), and allow site access.

A draft audit report is issued, and beneficiaries have 30 days for observations before the final report. Audits and reports are in the Agreement language, and sensitive information is treated confidentially.

The Ethics and Data Protection Decision Tree[3] can further support you in identifying and addressing potential ethics issues related to the data processing activities in the Sempre-Bio project.

[3] Ethics and Data Protection Decision Tree. https://ec.europa.eu/assets/rtd/ethics-data-protection-decision-tree/index.html

2.1.3. Consequences of non-compliance

If a beneficiary breaches any of its obligations under the relevant Article, the granting authority may reduce the grant (see Article 28 in the GA for more information). Such breaches may also lead to other measures described in Chapter 5 (for more information).

The granting authority can reduce a beneficiary's grant at the time of termination, final payment, or afterwards, if the beneficiary or related persons committed substantial errors, irregularities, fraud, or serious breaches under this grant or other EU grants. The reduction amount is proportionate to the seriousness and duration of the issues, calculated by applying an individual reduction rate to the accepted EU contribution. The beneficiary is formally notified of the reduction, the amount, and the reasons, and can submit observations within 30 days if they disagree. If the reduction leads to a recovery, the contradictory procedure with a pre-information letter, as outlined in Article 22, will be followed. The granting authority deducts the reduction amount and calculates the amount due, potentially making a recovery as per Article 22.

3. Data Protection

Data protection is designed to safeguard our right to privacy. It refers to the legal framework and technical measures implemented to ensure that all personal data are protected from unauthorized, unintended, or malicious use. Data protection encompasses measures related to data access, data storage, and data accuracy.

In the context of research, privacy concerns arise whenever personal data, whether in digital or physical form, are collected and stored. The primary challenge for researchers is to utilize and share data while simultaneously protecting identifiable information to guarantee personal privacy. The personal data required in research can include health information, genetic information, behavioural data such as criminal records, financial information, travel records, information on religious beliefs, sexual orientation, or ethnic identification records.

Data protection strategies in research should involve robust access controls, secure data storage and transmission protocols, data anonymization or pseudonymization techniques, and strict adherence to data minimization principles. Additionally, researchers must obtain informed consent from participants, implement data retention and disposal policies, and conduct regular privacy impact assessments to mitigate potential risks.

The Sempre-Bio project activities shall comply with the General Data Protection Regulation (EU) 2016/679 (GDPR). The GDPR is a comprehensive data protection law that was introduced by the European Union in 2016 and became enforceable on May 25, 2018. It is designed to strengthen and harmonize data protection rules across the EU, giving individuals greater control over their personal data and imposing strict obligations on organizations that collect, process, and store personal data.

Subject-matter and objectives of the GDPR

1. This Regulation lays down rules relating to the protection of natural persons with regard to the processing of personal data and rules relating to the free movement of personal data.

2. This Regulation protects fundamental rights and freedoms of natural persons and, in particular, their right to the protection of personal data.

3. The free movement of personal data within the Union shall be neither restricted nor prohibited for reasons connected with the protection of natural persons with regard to the processing of personal data.

3.1. Article 15 – Data Protection

The Sempre-Bio beneficiaries must carry out the action in compliance with the Data Protection requirements, as outlined in Article 15 of Annex 5, Section 2 – Rules for carrying out the action, in the Grant Agreement (GA).

According to the grant agreement of the Sempre-Bio project, in the section regarding Data Protection, the following paragraphs are relevant:

Data processing by the granting authority

Any personal data under the Agreement will be processed under the responsibility of the data controller of the granting authority in accordance with and for the purposes set out in the Portal Privacy Statement.

For grants where the granting authority is the European Commission, an EU regulatory or executive agency, joint undertaking or other EU body, the processing will be subject to Regulation 2018/1725.

Data processing by the beneficiaries

The beneficiaries must process personal data under the Agreement in compliance with the applicable EU, international and national law on data protection (in particular, Regulation 2016/679[4]).

They must ensure that personal data is:

- ➔ *processed lawfully, fairly and in a transparent manner in relation to the data subjects;*
- ➔ *collected for specified, explicit and legitimate purposes and not further processed in a manner that is incompatible with those purposes – adequate, relevant and limited to what is necessary in relation to the purposes for which they are processed – accurate and, where necessary, kept up to date;*
- ➔ *kept in a form which permits identification of data subjects for no longer than is necessary for the purposes for which the data is processed and*
- ➔ *processed in a manner that ensures appropriate security of the data.*

The beneficiaries may grant their personnel access to personal data only if it is strictly necessary for implementing, managing and monitoring the Agreement. The beneficiaries must ensure that the personnel is under a confidentiality obligation.

The beneficiaries must inform the persons whose data are transferred to the granting authority and provide them with the Portal Privacy Statement.

3.2. Consequences of Non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 28). Such breaches may also lead to other measures described in Chapter 5.

[4] Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation-GDPR).

4. Conclusions

Research Ethics and Research Integrity are fundamental pillars that underpin the credibility and excellence of research work. Building upon the achievements of Horizon Europe program aims to further integrate ethics and integrity into the research approach from the outset.

This deliverable serves as the first Report on Research Ethics and Data Protection, introducing the approach to ethics monitoring and an overview of the legal foundation, and outlines fundamental rules for ethical research conduct within the project. Ethics monitoring is an ongoing process that will continue until the end of the project, with the next Report on M42 documenting any ethical issues that arise.

The Sempre-Bio consortium recognizes the paramount importance of ethical considerations and is committed to upholding the highest ethical standards throughout the project. This includes ensuring transparency, obtaining informed consent, and safeguarding data protection, security, and privacy. The consortium will adhere to all relevant ethical principles, legislation, and guidelines. All consortium partners must remain cognizant of the ethical dimension and promptly communicate any ethical concerns. By fostering open dialogue and proactive problem-solving, the consortium can ensure ethical considerations are integrated into the research process, safeguarding the integrity and credibility of the project's outcomes.

5. References

The European Code of Conduct for Research Integrity. https://ec.europa.eu/info/funding-tenders/opportunities/docs/2021-2027/horizon/guidance/european-code-of-conduct-for-research-integrity_horizon_en.pdf

EU Grants: How to complete your ethics self-assessment: V2.0 – 13.07.2021

https://ec.europa.eu/info/funding-tenders/opportunities/docs/2021-2027/common/guidance/how-to-complete-your-ethics-self-assessment_en.pdf

REGULATION (EU) 2016/679 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation).

https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32016R0679

Ethics and Data Protection Decision Tree. https://ec.europa.eu/assets/rtd/ethics-data-protection-decision-tree/index.html