Deliverable D1.3 Ethics Plan

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WP Lead beneficiary	VTT
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Summary

This deliverable provides information on key ethical issues concerning research activities and a plan to carry out the action in compliance with ethical principles.

The Ethics plan is focused on the procedures adopted by the beneficiaries to carry out the action in compliance with (i) ethical principles (including the highest standards of research integrity as set out, e.g., in the European Code of Conduct for Research Integrity and (ii) applicable international, EU, and national law.

The Ethics Plan also includes a schedule to obtain and deliver all documents to satisfy the Ethics requirements raised in the Ethics Summary Report (EthSR) of the evaluated project proposal.

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1. Ethics tasks and deliverables in the Project Workplan

Ethics issues are specially dealt with in **WP1 (Management)** and **WP7 (Ethics)**.

In **WP1 (Management)**, the task **T1.3 Ethics management** covers the work done to ensure compliance with all ethics regulation and rules. The project follows the Horizon Europe ethics appraisal procedure. As task leader, VTT acts as Ethics mentor monitoring the ethics issues involved in the project and contributing to solving them. By the end of M3 an **Ethics Plan (D1.3)** (*this document*) will be prepared, detailing the forthcoming actions and responsibilities to ensure that ethics requirements are satisfied. The Ethics Plan will include a schedule to obtain and deliver all documents related to Ethics requirements.

WP1 also includes deliverables **D1.4 (Ethics report 1, M18)** and **D1.5 (Ethics report 2, M36)**. These reports will be produced by an external independent Ethics Advisor to assess the project's handling of ethical issues raised in the Ethics Summary Report in the evaluation of the project proposal.

In **WP7,** deliverable **D7.1 (OEI - Requirement No. 1, M12)** fulfills the requirement to appoint an external independent **Ethics Advisor.** The Ethics Advisor will assess the project's use of **Human cells**, as well as addressing **Health and Safety** of the research staff working with biological material, different solvents, and other chemicals in the project. The Ethics Advisor's assessments will be reported as deliverables **D1.4** and **D1.5**, already mentioned above.

2. Ethics, research integrity and EC ethics principles

2.1. Ethics

EC defines ethics in the following way:

"The EC perceives 'ethics' as including questions of legal and regulatory compliance as well as a branch of philosophy. It is part of a process of 'governance'. The consideration of ethical issues, starting at the conceptual stage of a proposal, enhances the quality of research, increases its likely social impact, promotes research integrity, promotes a better alignment of research with social needs and expectations and, finally, supports the societal uptake of the fruits of research because high ethical standards generally merit public trust. In this spirit, the Commission aims to build a relationship between the research process and ethics that is collaborative and constructive (rather than negative and inhibitive)."[1].

In Horizon Europe Programme, the guiding ethical principles are described in the EU regulation 2021/695, article 19:

"*Actions carried out under the Programme shall comply with ethical principles and relevant Union, national and international law, including the Charter and the European Convention for the Protection of Human Rights and Fundamental Freedoms and its Supplementary Protocols. Particular attention shall be paid to the principle of proportionality, to the right to privacy, the right to the protection of personal data, the right to the physical and mental integrity of a person, the right to non-discrimination and to the need to ensure protection of the environment and high levels of human health protection*."[2]

[1] Roles and Functions of Ethics Advisors/Ethics Advisory Boards in EC-funded Projects. https://ec.europa.eu/research/participants/data/ref/h2020/other/hi/ethics-guide-advisors_en.pdf

[2] https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:32021R0695#d1e2598-1-1

2.2. Research integrity

The EC has adopted Ethics and research integrity principles from The European Code of Conduct for Research Integrity[3] document provided by ALLEA - All European Academies –group. ALLEA document states that "*good research practices are based on fundamental principles of research integrity. They guide researchers in their work as well as in their engagement with the practical, ethical, and intellectual challenges inherent in research*".

- 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;
- **respect** for colleagues, research participants, society, ecosystems, cultural heritage and the environment;
- **accountability** for the research from idea to publication, for its management and organization, 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 and refrain from the research integrity violations described in this Code.

According to Grant Agreement Article 14, The beneficiaries must carry out the action in compliance with:

- ethical principles (including the highest standards of research integrity), and
- 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.

Naturally, continuous supervision and guidance is made by the project management regarding Research Integrity in the following contexts defined by ALLEA:

- Research Environment
- Training, Supervision and Mentoring
- Research Procedures
- Safeguards
- Data Practices and Management
- Collaborative Working
- Publication and Dissemination
- Reviewing, Evaluating and Editing

[3] https://allea.org/code-of-conduct/

2.3. Coordinator's organizational support for ethics and research integrity

The Coordinator (VTT) provides support for the project's ethics work in the following forms:

- VTT's ethics committee (including VP (General Counsel), DPO, Compliance Officer and RRI Manager)
- Research Integrity Advisors (RIAs)
- VTT OPINET online -course on research ethics and responsible conduct of research

Besides research integrity related themes, VTT's ethics committee will provide support for any ethical issues the project may encounter.

3. Ethics issues

3.1. Issues raised in the Ethics Summary Report (EthSR)

The Ethics Summary Report (EthSR) of the BIOASSEMBLER project proposal, produced by the EC's independent ethics evaluators, deemed the following ethics issue categories as relevant for the project:

- Humans
- Human Cells and Tissues
- Personal data
- Environment, Health, and Safety

As an overall analysis of the ethical dimension, the EthSR stated the following:

"*Given that the proposal is focused on novel manufacturing process for multiplex biosensors and their exploitation potential, no serious/complex ethics issues are present. Ethical issues related to the gathered data from humans participants (stakeholders, researchers) are foreseen and adequately dealt with (e.g. specific plan for an informed consent, appointed data manager, appointed DPO). Data acquisition is related to dissemination and exploitation activities in order to establish business opportunities for multiplex biosensors. Therefore an ethics assessment is not needed*."

In accordance with the above, the EthSR also stated that "*Issues related to Humans and Personal Data in regard to interviews with different stakeholders have been properly addressed in the Ethics table and in the Ethics Self-Assessment text*".

Thus, regarding the categories 'Humans' and 'Personal Data', the EthSR sees that the ethical issues have been properly addressed.

However, regarding 'Human Cells' and 'Health and Safety', the EthSR sees that the ethical issues have not been addressed. Therefore, it mandates an **external independent Ethics Advisor** to be appointed and consulted on these issues, and that a report must be submitted by the ethics advisor each reporting period.

In the following sections, we describe how the BIOASSEMBLER project will deal with the ethical issues in each of the four categories identified in the EthSR. Additionally, we will also study whether there are any ethical issues in the category 'Artificial Intelligence' that need to be addressed.

3.2. Humans

The project's task 6.5 (Socioeconomic Analysis of Multiplexed Biosensors) involves contacting and interviewing human participants. All participation is voluntary and is done with fully informed consent. Minors are not involved in the study. Extensive description of the study methods and the adherence to the highest

ethical standards were given in the self-assessment form in the proposal Part A. This information was deemed adequate in the Ethics Summary Report (EthSR):

"*Issues related to Humans and Personal Data in regard to interviews with different stakeholders have been properly addressed in the Ethics table and in the Ethics Self-Assessment text*."

Action to take:

A document describing 1) the participatory study methods and 2) compliance with ethical principles and legal obligations will be produced for the external independent Ethics Advisor.

The external independent Ethics Advisor will evaluate the document on the participatory study methods and add his comments, recommendations, and conclusions to it. The commented version will form part of the Ethics Advisor's report (Deliverable D1.4, Ethics report 1, due M18).

3.3. Human Cells / Tissues

The Ethics Summary Report (EthSR) raised an issue on the project's plan to use a cell line of human origin for recombinant antibody production:

"*Human Cells: Cell line HEK293, which is composed of human embryonic kidney 293 cells, will be used in this project. Origin of these cells (e.g. whether they stem from this project, another project, commercial, imported from a non-EU country or similar) is not sufficiently clear. Origin of the human cell lines should be clarified*."

Action to take:

We will address the question of the origin of the cell line and produce the necessary documentation and other information supporting the legitimate use of the cell line in the project. This information will also be provided to the external independent Ethics Advisor, who will evaluate its validity. The Ethics Advisor will also be given an opportunity to interview Partner 4 – Abcalis on the matter.

The external independent Ethics Advisor will produce an evaluation of the case (including comments, recommendations, and conclusions) in a report at the end of the first period of the project. (Deliverable D1.4, Ethics report 1, due M18).

3.4. Personal data

The project's task 6.5 (Socioeconomic Analysis of Multiplexed Biosensors) involves collecting personal data about the study participants, however, under fully informed consent. The principle of minimum and strictly necessary data will be applied, to be used for research and analysis purposes only. Personal data, such as age and gender, will be used in aggregated form only. A detailed description of the data handling procedures was given in the self-assessment form in the proposal Part A. This information was deemed adequate in the Ethics Summary Report (EthSR):

"*Issues related to Humans and Personal Data in regard to interviews with different stakeholders have been properly addressed in the Ethics table and in the Ethics Self-Assessment text*."

Action to take:

A document describing 1) the data handling procedures and 2) compliance with ethical principles and legal obligations will be produced for the external independent Ethics Advisor.

The external independent Ethics Advisor will evaluate the document on the procedures for personal data handling and add his comments, recommendations, and conclusions to it. The commented version will form part of the Ethics Advisor's report (Deliverable D1.4, Ethics report 1, due M18).

3.5. Environment, Health, and Safety

The Ethics Summary Report (EthSR) raised an issue on the project's planned work with biological material, different solvents, and other chemicals, as well as nano-bio technologies:

"*Health and Safety: This proposal includes work with biological material, different solvents and other chemicals, which are used during research, testing and validation steps. It also involves new methodological approaches and nano-bio technologies. Health and safety issues for research staff have not been addressed*."

Action to take:

We will address the potential health and safety issues for research staff by making sure that appropriate safety practices are in place with each of the beneficiaries which perform laboratory work in the project. Documentation of the relevant safety measures will be collected from the beneficiaries' Occupational Safety and Health Officers or other persons in the organization who oversee the safety and health of the laboratory workers. Any potential special hazards associated with the project work will be evaluated, and appropriate measures will be implemented as necessary. The implemented safety measures will be documented, and all documentation will be offered to the external independent Ethics Advisor, who will evaluate its validity. The Ethics Advisor will also be given an opportunity to interview the beneficiaries as he sees necessary.

The external independent Ethics Advisor will produce an evaluation of the health and safety issues (including comments, recommendations, and conclusions) in a report at the end of the first period of the project. (Deliverable D1.4, Ethics report 1, due M18).

3.6. Artificial Intelligence

In the Task T6.4 (Data analysis, AI and Big Data), the project will explore the potential use of artificial intelligence in the processing and analysis of biosensor data. However, we don't anticipate actual development, deployment and/or use of artificial intelligence in the project. Rather, the task consists of a survey of the different possibilities of AI that could enhance the use of multiplex biosensors in the future. The survey will likely encounter use cases that involve the processing of personal information, such as health data. Also, the safety of AI-based automated decision systems may require special attention. Therefore, for all potential AI use cases, the survey should always consider their ethical implications, and where appropriate, refer to the ethical principles described in section 2.1.

Action to take:

In the survey of potential AI methods for the processing and analysis of biosensor data, special attention will be paid to their ethical implications. Any identified ethics issues will also be communicated to the external independent Ethics Advisor, who will be consulted regarding these issues.

The external independent Ethics Advisor will evaluate the ethics issues identified in the Task T6.4. The Ethics Advisor will include in his report comments, recommendations, and conclusions on the issues. (Deliverable D1.5, Ethics report 2, due M36).

4. Schedule of actions

Ethics category	Action / Product	Responsible partner	Due
OEI	Appointment of Ethics Advisor	1 - VTT	M2
Humans	Description of procedures for interviews and other participatory studies	6 - CES	M6
Human Cells	Clarification of Origin of cell line	4 - Abcalis	M4
Personal Data	Description of data handling procedures	6 - CES	M6
Health & Safety	Document of safety & health protection measures for lab personnel	All except 6 - CES	M6
OEI	Ethics Report 1	Ethics Advisor	M18
Artificial Intelligence	List of ethics issues identified in AI survey	1 - VTT	M20
OEI	Ethics Report 2	Ethics Advisor	M36