Deliverable D19.5
Ethics Independent Assessment

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1.0	17/11/2024	Final version submitted to the JU

Report contributors		
Name	Beneficiary Short Name	Details of contribution
Stéphanie Gauttier	Independent Ethics Advisor	Drafting of the report
Iñaki Díaz	CEIT	Formal Proofreading
Ton Visser	NS	Internal review
David Villalmanzo	ADIF	Quality check and official submission to the JU

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1. Executive Summary

This document presents the context in which the collaboration with the Independent Ethical Advisor is taking place. It analyses any ethical issue arising from Work Package (WP) 19 (Exoskeleton and AR for Railway Maintenance) and the way they have been mitigated by the project partners so far. The analysis pertains mostly to the work done in deliverable D19.1 (Workplace analysis and specifications). It shows that the FP3-IAM4RAIL consortium has high awareness of ethical issues. The work done in Task T19.1 (Workplace analysis and specifications) also anticipates potential risks related to the use of the exoskeleton, which is useful in thinking the activities of tests planned in Tasks T19.3 (AR tools and exoskeleton development and prototyping) and T19.4 (Technology Validation and Demonstration). The Independent Ethical Advisor does recommend to maintain the efforts and increase transparency on the protocols approved, the sample characteristics, and the way participants' rights are explained to them. Given the efforts made by the consortium so far, there is very little risks in the development of the project.

2. Abbreviations and acronyms

Abbreviation / Acronym	Description
WP	Work Package

3. Background

The present document constitutes the Deliverable D19.5 “Ethics Independent Assessment” in the framework of the Flagship Project FP3 – IAM4RAIL as described in the EU-RAIL MAWP. The deliverable is part of the WP19 of the IAM4RAIL project and reports main work and conclusions of WP19 (Exoskeleton and AR for Railway Maintenance).

4. Objective/Aim

The aim of WP19 is the development of novel and smart assistive tools to support workers in their daily railway maintenance tasks. More specifically, in WP19 technology will be developed to improve human safety and skills in workplace through Exoskeleton and Augmented Reality systems. The independent ethical review analyses any ethical issue stemming from this research activity, the efforts made by the partners to mitigate them, and provides further recommendations. This analysis is made based on the excerpts of the Grant Agreement shared with the Independent Ethics Advisor, the deliverable D19.1 (Workplace analysis and specifications), and information pertaining to the use-case development.

5. Introduction

The present document constitutes the Deliverable 19.5 “Ethical Independent Assessment” for the FP3-IAM4RAIL project. The Ethical Independent Advisor, Pr. Dr. Stéphanie Gauttier, was appointed over the course of 2023-2024 by the consortium, with a contract signed in April 2024. The Ethical Independent Advisor declares having to no conflict of interest to perform the assessment (see Appendix 1) and shows proofs of competency in the domain (see Appendix 2).

The FP3-IAM4RAIL project is constituted of 21 Work packages (WP). It aims at developing and testing the next generation of Intelligent and Integrated Rail Asset Management. These innovations are meant to minimize the life cycle costs of assets, extend their lifetime, as well meet the safety requirements prevailing in this area. The project also encompasses goals pertaining to improving cost efficiency and reducing harm in relation to the environment. It should improve the reliability, availability, and capacity of the railroad system overall, thus benefiting to all railway users in Europe. As such, the project aligns with ethical values for the common good: safety, utility, environmental sustainability.

The object of this report concerns WP19 in particular, which is entitled ‘Exoskeleton and Augmented Reality for railway maintenance’. This work package comprises activities ranging from workplace analysis and specifications to the design of tools and their validation. The analysis of the Independent Ethics Advisor is meant to consider the elements related to the development and testing of the exoskeletons only, as per the assignment given by the contact point in the consortium, Inaki Diaz. The Augmented Reality activities are therefore not considered in this report. This report constitutes deliverable D19.5, the Ethical Independent Assessment.

According to these documents, the technologies developed in WP19 are meant to support workers in their daily tasks. The presentation of WP19 in the Grant Agreement puts emphasis on values such as human safety and skills development. Users are put at the centre of all design-related considerations, as the consortium sets out to gather user needs and requirements before design, and then to evaluate how the technology works. The analysis conducted by the Independent Ethics Advisor takes notes of the inclusion of the aforementioned values into design, and then focusses on the way in which human participation in the project is facilitated. First the activities already performed are reviewed, then advice is given to develop future activities.

6. Overview of the project and related ethical dimensions to analyse

6.1. Planned activities

The work package 19 comprises 4 deliverables and related activities, as summarized in Table 1. At the date of completion of this deliverable, activities have been performed on deliverable D19.1, on which our analysis will focus. We do not consider deliverable D19.2 which focuses on technical development. We consider recommendations for deliverable D19.3 and D19.4, which will be developed in 2025-2026, which we outline in chapter 7. It is however noteworthy that the consortium has anticipated potential issues through the means of a risk assessment performed in deliverable D19.1.

Deliverable	Objective	Methodology (as per the Grant Agreement)	Ethical considerations	Mitigation measures
19.1 Workplace analysis and specifications	Study workers' needs in terms of ergonomics and task guidance support	Use case development; Visual Observation, Questionnaires, Interviews, Historical Data	Values embedded in the use case; Awareness of ethical risks; Free and informed consent to participate from workers; Processing Personal Data; Data processing and Storage; Consequences to (non)-participation; Location of data collection; Topics of enquiry; GDPR and participants' rights.	Approval from Research Ethics Committee; Anonymous data collection; No sensitive data; Minimal data collected; Voluntary Participation; Transparency on data processing and storage.
19.2 AR Architecture and Exoskeleton Concept Design	Define the concept of an upper-body exoskeleton	*This deliverable focuses on technical development, without planned participation of workers or other human beings.*		
19.3 AR tools and Upper-body Exoskeleton development and prototyping	Design the exoskeleton and prototype it	Tests in lab and in-situ with real users	Values embedded in the use case; Awareness of ethical risks; Free and informed consent to participate from workers; Processing Personal Data; Data processing and Storage; Consequences to (non)-participation; Location of data collection; Topics of enquiry; GDPR and participants' rights; Testing emerging technologies.	A risk assessment analysis is embedded in 19.1 in preparation. Further ethical considerations need to be had as the tests are designed.
19.4 Validation and result	Validation of Exoskeleton systems	On-site		

Table 1. Planned activities from WP 19 and related ethical concerns for analysis

The output of deliverable D19.1 'Workplace analysis and specifications' leads to the identification of a use-case to be addressed. Specifically, the development of the exoskeleton aims at addressing issues related to musculoskeletal disorders in the work environment, which the project partners describe as the leading cause of sick leave in work accidents and occupational diseases. These musculoskeletal disorders are related to overexertion, which comes from how physical and

exhausting the work is. The consortium justifies why they require new developments, in comparison to other existing solutions meant for very controlled and clean environments, to enable the use of exoskeletons for railway workspaces in all safety. This highlights the need for new data collection.

The intent, at the onset of the project, was therefore to identify how exoskeletons could support workers. The upper body area is described as being especially important. The consortium highlights how the project aligns with wide socio-sanitary and business related considerations, relating to the common good. It also shows at multiple occasions high considerations for users:

- It highlights the need to consider for workers' individual situations, to preserve their autonomy, personal lives, and future employability.
- It provides a strategy combining passive and active modules for the exoskeleton, which should provide optimal support to workers.

As such, human participation into the project does not create specific risks of harm if the developed exoskeleton is functional and complies with traditional safety standards. On the contrary, workers are encouraged to voice their needs and then make sure the tool developed fits their requirements.

When it comes to the realizations of deliverable D19.1, the project partners have put the emphasis on the diversity of viewpoints, collecting data from several locations in Europe through workplace analyses and questionnaires.

Collecting data from workers is sensitive: potential participants are also bound to the project partners by a work contract, and may not see their participation as voluntary. They may also fear consequences for their answers. As such, particular care must be applied when making them participate. The topics raised, when it comes to health and work practices, can require further privacy impact assessment. However, the consortium has taken the necessary actions to protect participants by:

- Obtaining the ethical approval from the Research Ethics Committee of the University of Navarra in Spain and thus ensuring a third-party expert opinion on the actions to be undertaken;
- Translating the questionnaire into local languages, making it easier for workers to participate;
- Making participation voluntary;
- Recording answers in an anonymized manner only, implying there is possible negative consequences linked to (non)-participation;
- Not collecting any form of personal data;
- Asking questions related to needs for future exoskeletons, not asking about the current ways of performing tasks and not asking health-related questions or any other sensitive data point;
- Creating a short questionnaire, asking only for what was necessary to develop the use-case;
- Processing data in an aggregated manner only;

- Being specific about the duration for which the data would be stored;
- Mentioning the EU General Data Protection Regulation.

While there is no mention of how workers have given their consent to participate, it is noteworthy that with the aim of the project being to help workers in performing their tasks in a safe environment, it can be considered that data is processed under the legal basis of legitimate interest. The use of historical data does not open ethical issues. The data is not shared beyond European borders.

Going one step further, the partners have produced a risk assessment analysis, encompassing physical, safety, cognitive and psychological, environmental, regulatory, technological and competencies-related risks. They evaluate each risk and give it a score. For each risk they identify mitigation measures, ranging from technical solutions (robust power management systems) to social ones (targeted training). This should ensure a responsible development of the exoskeleton.

6.2. Remaining considerations

The activities that could be analysed in the frame of this deliverable D19.5 appear to be performed with the respect of human participants and of research ethics in mind. Several questions pertaining to the sample characteristics (gender, diversity), the way consent was obtained, and the scope of the protocol submitted to the Research Ethics Committee, are still open. Participants' rights as per the General Data Protection Regulation must be detailed to them prior to consenting to participation. These points can easily be treated when considering the development of the in-lab and in-situ tests.

7. Observations from the independent ethics advisor

The project, despite delays in contracting the Independent Ethics Advisor and then receiving the Ethics Review Report, does not present significant ethical issues. Indeed, the aims of the project align with the respect of values such as safety, wellbeing, sustainability.

Besides, the project partners have shown high awareness of ethical considerations: they have received the approval of an Ethical Committee in Spain for the activities described in WP19, developed their risk assessment, and show consideration for human participants in their research as well as future users. The consortium partners show anticipation of relevant ethical issues (risk assessment, ethical approval from an external party), inclusion of stakeholders (gathering requirements and testing the tools with workers), and reflexivity (risk assessment). The commitment of the consortium to obtain approval from a Research Ethics Committee is also laudable. These activities show a high engagement of the consortium, which seems to be appropriating the notion of ethics in research and development, moving from an initial description of work to actually embedding ethics in the development of traditional deliverables for an engineering project. As such the assessment of the current activities is positive.

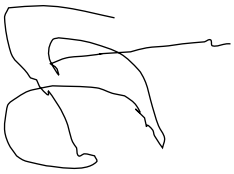
The consortium is encouraged to consider the following elements when preparing for the in-lab and in-situ tests for deliverables D19.3 and D19.4:

- Considerations on diversity and gender: Gender is one of the pillar of Responsible Research and Innovation. The consortium needs to show whether they enable female workers to respond and use the exoskeleton or not. It is noteworthy that to date most studies on the use of exoskeletons focus on male users. Beyond gender, one would wonder how the diversity of the workforce is represented in the participant sampled. The sampling strategy is of importance to make sure that the project is not targeting vulnerable populations.
- Ethical approval from the Research Ethics Committee: Provide the text of your application with the description of the entire research protocol.
- Get advice on the information sheets and consent forms sent to workers, to ensure all compulsory information, including about participants' rights over their data as per the General Data Protection Regulation, is laid out.
- Using a device is different from responding to a questionnaire, which can create new risks for participants, especially with a device which has not been certified in any way. Some of these risks are mentioned in deliverable D19.1, yet the consortium is encouraged to reconsider the risks prior to launching the tests.
- An approach to measuring KPIs was shared, however the consortium is invited to share any KPI related to human activity, as they may require collective sensitive information.
- If images are shot during the tests, this will mean that personal data is collected. The consortium is invited to consider this when obtaining consent, and to develop any necessary addendum to enable the use of the pictures or videos thus obtained.

The Independent Ethical Advisor remains at the disposal of the consortium to support them in their endeavour to implement their project in the most ethical manner.

8. Signature of the independent ethics advisor

Prof. Dr. Stéphanie Gauttier
June 11th 2024

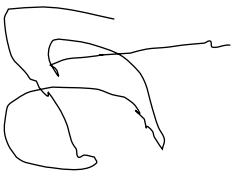


9. Appendix 1. Declaration of absence of conflict of interest

The undersigned Stéphanie Gauttier appointed as Independent Ethics Advisor for the IAM4RAIL project declare that

- She will execute her responsibilities in full independence of other professional and academic commitments.
- She is not affected by any conflict of interest arising in particular from any economic interest, from family of other personal links, or from any other relationships or common interests which may compromise the independent nature of the report provided.
- There are no other professional or financial constraints to carry out the required assignment, or that would compromise the independent nature of the report provided.
- She will notify the project coordinator without delay of the above situation changes, particularly in such a way as to compromise the independent nature of the report.
- She will not reveal any information about the project activities and its outcomes without the express written approval of the beneficiary/ies or the Europe's Rail Joint Undertaking.

Stéphanie Gauttier
May 10th, 2024



10. Appendix 2. Curriculum Vitae

Prof. Dr. Stéphanie GAUTTIER

EDUCATION

2023: Habilitation à diriger les recherches (Accreditation to Supervise Research), University of Nantes, France
Title of the manuscript: "Acceptance and Usage of Human Augmentation Technologies: Toward an Embodied Vision of Information Systems"

2011-2017: Ph.D. in Management Sciences, University of Nantes, France
Thesis Title: 'Conditions of Moral and Functional Acceptance of Human Enhancement Technologies – Consumer Experience of Augmented Reality'

2006-2011: Sciences Po Rennes, France
MBA with honors, Economics and Finance, specialization in "Organizational Communication."
Master's degree with honors, Political Science, specialization in public administration (sociology)
Bachelor's degree in public administration (without specific mention)

CURRENT POSITION

September 2023 – Present: Associate Professor (Permanent), Team Leader "Information Systems for Society"
Department of Management, Technology, and Strategy, Grenoble Ecole de Management, France

PREVIOUS ACADEMIC AND RESEARCH POSITIONS IN APPLIED ETHICS

October 2019 – September 2023: Assistant Professor (Permanent), Team Leader "Information Systems for Society," Department of Management, Technology, and Strategy, Grenoble Ecole de Management, France

March 2018 - October 2019: Marie Curie Fellow IF (GLASNOST), Department of Philosophy, University of Twente, Netherlands

April 2017 - March 2018: Postdoctoral Researcher (SATORI projects on research ethics, Responsible Industry, and Policy), Department of Philosophy, University of Twente, Netherlands

INSTITUTIONAL RESPONSIBILITIES AND TRUST COMMITTEES RELATED TO ETHICS

1. **Ethics Manager of the STREAM project**, overseeing the production of the independent ethical expert's report on the project.
2. **Independent Ethical Advisor for Rail4Earth** in 2023.
3. Creator and **Head of the Research Ethics Committee at Grenoble Ecole de Management**, since 2023.

4. Managed the **creation of a code of conduct for Marie Curie Alumni Association in 2020.**
5. Responsible for **teaching modules on Digital Sustainability since 2022 and Ethics, Technology, and Society** since 2023 at Grenoble Ecole de Management.
6. Teaching an Introduction to **Technology Ethics at Polytech Nantes since 2019**.

EXPERIENCE IN FINANCED PROJECTS

Evaluation of European projects (COST, European Commission).
Expertise in project management and deliverable writing for European projects.

Current Financed Projects

1. ReMo: European Commission – COST Action, 445,000 Euros, March 2020 – September 2024, Management Team, Vice-President.

Past Financed Projects

1. STREAM: European Commission – S2R, 2.9 million Euros (123,250 euros for GEM), December 2020; June 2023, Consortium Member for GEM, Manager of ethical issues, Participation in management, and Responsible for 2 tasks.
2. OSCAR: European Commission – Erasmus +, 475,000 Euros, September 2020 – September 2023, Consortium Member, Expert in the proposal.
3. Digital Twins: PHC Van Gogh (Campus France), 2,500 Euros, 2021, Project Coordinator.
4. GLASNOST: European Commission – H2020 – MSCA IF, 168,000 Euros, March 2018-March 2020 (interrupted in September 2019), Individual Application.
5. Cyborg Observatory: JSPS, 7,500 Euros, 2019/2020, Consortium Member.
6. GLASNOST: Government of Ireland, 99,000 Euros, 2018-2020, Individual Application.
7. SAMI: CPER, 7,500 Euros, September 2018, Associated Researcher.

Production of European Deliverables

Including the first 5 in the railway domain:

1. Gauttier, S.; Lugova, A. 2023. Deliverable D 6.1 Ethical Acceptability, STREAM.
2. Lugova, A.; Gauttier, S. 2023. Deliverable D 6.2 Cost Benefit Analysis, STREAM.
3. Gauttier, S.; Nyholm, S., 2021. Deliverable D 8.3 Independent Ethics Advisor Report, STREAM.
4. Masullo, L.; Trentini, D.; Morata, M. ; Vives, E. ; Di Natali, C. ; Toxiri, S. ; Gauttier, S. ; De Vito, P; Hugon, D. ; Landini, A. 2021. Deliverable D 1.2 (WP1) Requirements and KPIs for the Modular Multitasking Powered Exoskeleton User, Safety, Regulatory, Ethical, and Technical Requirements, STREAM.

5. Vives, E; Morata, M.; Masullo, L; Gauttier, S.; Hugon, D; Koivumäki, J; Mattila, J; Hulttinen, L. 2021. D 1.1 WS 1 - Requirements & KPIs for generic On-Track Autonomous Multi-purpose Mobile Manipulator: User, Safety, Regulatory, Ethical, and Technical Requirements, STREAM.
6. Kismihók G., Gaspar I., Delaney J., Schroijen M., Tavakoli M., Faraji A., Abu-Rasheed H., Gauttier S., Mol S., Weber C., Santa Maria A. R., Jolivet R., 2022. OSCAR Conceptual and Technical Framework for Researcher Well-being and Career Development Training and Mentoring, European Commission Erasmus Plus program.
7. Kismihok, G., Cahill, B., Gauttier, S., Metcalfe, J., Mol, S.T., McCashin, D., Lasser, J., Günes, M., Schroijen, M., Grund, M., Levecque, K., Guntrie, S., Wac, K., Dahlgaard, J., Adi, M.N., Kling, C. 2021 Researcher Mental Health and Well-being Manifesto, ReMO Cost Action, CA19117.
8. Gauttier S., Brey P., Milam P.-E., 2019. Harmful internet use Part II, Impact on culture and society - Study, Directorate-General for Parliamentary Research Services (European Parliament).
9. Rodrigues S., Sattarov F., Wright D., Porcari A., Warso Z., Birkavs E., Gauttier S., Reijers W., Trescher D., Ovadia D., Koivisto R., Kari M., Griessler E., Callies I., Bøgh S., Bencin R, 2017. Initiatives and policy developments at local, national, and European levels, European Commission.
10. Leinonen A., Koivisto R., Tuominen A., Douglas D., Gurzawska A., Jansen P., Kapeller A., Gauttier S., Brey P., 2017. Roadmap towards adoption of a fully developed ethics assessment framework, SATORI, European Commission.
11. Gauttier S., Søraker J., Arora C., Brey P., Mäkinen M., 2017. Models of RRI in Industry, European Commission.
12. Responsible-industry (2017), Benefits of Responsible Research and Innovation in ICT for an ageing society.
13. Responsible-industry (2017), Guide for the implementation of the Responsible Research and Innovation (RRI) in the industrial context.
14. Responsible-industry (2017), EU Policy recommendations for Responsible Research and Innovation in Health and Ageing.
15. SATORI (2017), Deliverable 9.3, Key policy recommendations and policy briefs.
16. SATORI (2017), Deliverable 9.1 Initiatives and policy developments at local, national, and European levels.

INTELLECTUAL PRODUCTION

An overview of my academic production can be found here:
https://scholar.google.com/citations?user=thfGB3wAAAAJ&hl=fr