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D1.6

Ethics management Plan

STEEL Applications for Low Investment manufacturing of high Value Elements

Lead beneficiary:
CIDAUT

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List of Abbreviations

Acronym	Description
AI	Artificial Intelligence
CBRN	Chemical, Biological, Radiological, or Nuclear
DoA	Document of Action
EC	European Commission
ESR	Early-Stage Researchers
EU	European Union
GMM	Genetically Modified Micro-organism
GDPR	General Data Protection Rules
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals
VPN	Virtual Private Network



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1 Executive Summary

This deliverable D1.6 establishes the ethical management guidelines that will drive STEEL-ALIVE during its lifetime. They are based on the existing EU regulations, directives, guidelines, and recommendations on ethical issues in research and research integrity principles. As such, it identifies the main ethical standards and requirements to be applied on the following domains: human participation in research, data protection, health and safety, participation of non-EU countries, Artificial Intelligence, and misuse of research results. Following a self-assessment process, no major ethical issues have been identified in any of the aforementioned categories. This ethics management plan will be periodically reviewed as the project evolves, to make sure that research is carried out following the highest ethical standards.



2 Introduction

Integrity and ethics in research are key components and a prerequisite for achieving excellence in research and innovation. The key goal is to build and sustain trust in science and innovation, and to encourage and enable researchers and innovators use the ethics by design approach to bring meaningful added value: the development of knowledge, technology and applications that improve people's lives, prospects and possibilities (1).

According to the EU Regulation 2021/695 (2) establishing Horizon Europe, particular attention shall be paid 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 a person
- The right to non-discrimination
- The need to ensure protection of the environment
- The need to ensure high levels of human health protection

To ease the compliance with the ethics dimension of the project, the EC has designed an ethics self-assessment that helps the beneficiaries to identify and deal with ethics issues that may arise from the project, in the following areas:

- Human embryonic stem cells and human embryos
- Human participants
- Human cells and tissues
- Personal data
- Animals
- Non-EU countries
- Environment & Health and Safety
- Artificial Intelligence
- Potential misuse of results

All these aspects are covered in the following chapters of this report.

3 General ethics requirements

Horizon Europe, as well as other European Programmes, requires all participants and beneficiaries to comply with the ethics and research integrity obligations to the “highest ethical standards” and “EU values”.



The partners will respect the fundamental principle of research integrity, as set out in the European Code of Conduct for Research Integrity (3), which implies to guarantee:

- 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 manner.
- 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
- Openness, reproducibility and traceability from the research to the extent possible.

Although not foreseen in the DoA, if during the project execution any action raising an ethical issue appears, the partners will make sure to obtain all approvals or any other mandatory documents needed for implementing the task, notably from any ethics committee or other bodies such as data protection authorities. These documents will be kept on file and be submitted upon request by the coordinator to the granting authority.

Regarding the potential misuse of research results, it refers to those research that is carried out with benign intention, but if used for the wrong purposes, has the potential to harm humans, animals, or the environment, and may have substantial negative impacts on the security of individuals, groups or states (4). According to the guidance note published by the EC, the research most vulnerable to misuse is research that:

- generates knowledge, materials and technologies that could be used for criminal or terrorist purposes.
- could result in the development of Chemical, Biological, Radiological or Nuclear (CBRN) weapons or any method for their delivery.
- involves developing surveillance technologies that could curtail human rights and civil liberties.
- involves minority or vulnerable groups or develops social, behavioural or genetic profiling technologies that could be misused to stigmatise, discriminate against, harass or intimidate people.
- develops materials/methods/technologies and knowledge that could harm humans, animals or the environment if they were released, modified or enhanced.

A first assessment performed by the coordinators indicates that **there is no evident risk of misuse resulting from the research activities performed within STEEL-ALIVE**. In any case, the risk of misuse of research can never be fully eliminated, and therefore it must be minimised by recognising the risks and taking the right precautions. As such, the following actions may be applied during the course of the project for the sake of precaution: classification of certain



deliverables or specific sections of them, limiting the dissemination of sensitive information, or publishing only a part of research results.

4 Human ethics considerations

According to the Grant Agreement, the beneficiaries must ensure that the activities under STEEL-ALIVE do not:

- Aim at human cloning for reproductive purposes
- Intend to modify the genetic heritage of human beings which could make such changes heritable
- Intend to create human embryos solely for the purpose of research or for the purpose of stem cell procurement
- Lead to the destruction of human embryos

In relation to this, no human investigative activity is planned during the project activities by any partner or in a context organized by an institution external to STEEL-ALIVE and hence no consent procedure is applicable or requested. Human participants are not involved especially in case studies or as research subjects. Research and studies do not involve any physical interventions, invasive techniques, nor will any samples be taken from humans. In consequence, **no specific human related consent procedures have to be implemented for the participation of any humans**, nor do informed consent/assent forms and information sheets (in language and terms intelligible to the participants) must be kept on file. Also, no opinions or approvals by ethics committees and/or competent authorities for the research with humans are needed or are foreseen during the project.

5 Protection of personal data

“Personal data” refers to any private or professional information that relates to an identified or identifiable natural person. “Processing of personal data” means any operation (or set of operations) which is performed on personal data, either manually or by automatic means, including collection, recording, organization and storage, dissemination etc.

According to the guidelines for data protection in research (5), the following categories of personal data can be identified:

- Personal data (e.g. name, home address, e-mail address, location data, etc.)
- Sensitive data (e.g. religious beliefs, political opinions, medical data, etc.)
- Previously collected personal data.



According to these definitions and categories, it is important to remark that **the final outcomes of the STEEL-ALIVE project will not contain primary data and will be devoid of any personal or privacy-sensitive data.**

In any case, STEEL-ALIVE is committed to complying with the General Data Protection Regulation, GDPR, for collection, storing and managing research data (Regulation 2016/679 (6) 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). STEEL-ALIVE researchers will not collect personal data, such as names, farm identities and addresses. No sensitive data, such as that on health, sexual lifestyle or the religious conviction of people will be collected. No personal data is necessary to achieve the research tasks and hence will not be collected.

As coordinator partner, CIDAUT will monitor all issues relating to data protection. Its Data Protection Officer will be in charge of the anonymization of the data if needed, in such a way that the personal data of individuals participating in the research activities will only be used under strict confidentiality conditions and potentially published solely as aggregated statistics and under no circumstances as individual data sets.

Although no major changes are expected during the project duration in what concerns personal data protection, a screening assessment will be conducted at least annually to identify potential ethics risks on the basis of the following points:

- The processing of personal data which could result in a risk of physical harm in the event of a security breach.
- Processing of biometric or genetic data.
- Use of innovative new technologies (such as Artificial Intelligence) in (personal) data processing.
- Large scale processing of special category data / data relating to sensitive data, such as religious beliefs, political opinions, criminal convictions and offences.

Proactive solutions and safeguards to the above points involve:

- Technical. Data anonymization, data security and pseudonymization (e.g., encryption, masking), specific solutions such as differential privacy, Virtual Private Networks (VPNs) and onion routing.
- Regulatory. Ethical policies and frameworks, including guidelines, oversight bodies, different approaches to data ownership and licensing, develop ongoing consenting procedures.



6 Health and safety considerations

STEEL-ALIVE also addresses the ethical points for research activities that could potentially involve physical or psychological harm of the research participants. It is recognised that the health and safety of all human participants in research, either as subjects, investigators or uninvolved third parties, must be a priority in all kinds of studies. The kinds of risk to researcher safety vary according to the nature of the discipline, the topic and the research site. Only the 'researcher in the field' can fully assess safety concerns and/or their willingness to tolerate risks.

However, research in both familiar and unfamiliar settings can involve added safety concerns. Even in familiar settings, surprising, non-routine things can happen which pose safety risks. Moreover, in certain types of research, the risk of harm to the researcher is caused by the topic of study or by the actions of the researchers themselves. Lack of caution or failure to obey standard procedures may lead to physical or psychological harm.

STEEL-ALIVE research activities will comply with applicable international, EU and national law regarding public health control and safety at work and the EU Directive 2006/25/EC (7) of the European Parliament and of the Council of 5 April 2006 on the minimum health and safety requirements. Researchers will be advised, warned and even removed from dangerous situations if the research working environment is considered hazardous either by environmental conditions or by the equipment used.

STEEL-ALIVE research activities should do no harm, either physical, psychological or moral. The concept of 'do no harm' can be differentiated along several lines. The activities undertaken by STEEL-ALIVE do not include research conducted on humans, as such the concept of 'do no harm' does not apply to such individuals. The 'do not harm' concept applies, though, to researchers themselves who may be involved in hazardous or troublesome activities in carrying out the research. Furthermore, research activities can imply a variety of bystanders either involved or uninvolved in the research. All of these types of participants have the right to protection.

No physical or psychological harm should result from the research being carried out. Physical and psychological harm can involve several different groups that find themselves implicated by our research. Project related research will not provoke moral harm, we mean harm to one's dignity. This means harm to one's feeling of autonomy, worthiness, identity or sense of moral self, including degrading procedures, humiliation, either direct or indirect.

All research activities in AVANGARD do not involve actions pertaining to directive 2000/54/EC (8) (on the protection of workers from risks related to exposure to biological agents at work) , to directives 2009/41/EC (9) and 98/81/EC (10) (on the contained use of Genetically Modified Micro-organisms – GMMs), and to guidance on nanomaterials/nanoforms that has been published in the REACH regulation (11).

Due to the nature of the research activities to be performed, STEEL-ALIVE research activities **do not involve the use of elements that may cause harm to humans, including the research staff.**



7 Potential activities in non-EU countries

In this section, the ethical points for research activities that could potentially involve exploitation of research participants and /or local resources of non-EU project partners as well as imports and exports of materials and data between the EU and non-EU countries are addressed.

The STEEL-ALIVE project will ensure that any conducted activities during the research will not entail any exploitation of research participants or local resources of non-EU countries neither will it entail risks to researchers and staff. Also, STEEL-ALIVE is committed to regulate any ethics issues that may raise when research involves directly or indirectly non-EU countries. This is the case when:

- research activities are conducted, partially or wholly, in a non-EU country
- participants or resources come from a non-EU country
- material is imported from or exported to a non-EU country.

Being outside the reach of European laws and standards, such research can raise specific ethical issues (particularly in developing countries), such as:

- exploitation of research participants
- exploitation of local resources
- risks to researchers & staff
- research that is prohibited in the EU.

In this regard, there are not any partners belonging to non-EU countries, so in principle no direct involvement of such countries in the research activities is expected. Also, no import and export of materials and/or data is foreseen. If that would be the case at any point during the project, the Coordinator will ensure that the appropriate agreements are put in place and documented. In general, STEEL-ALIVE project is favourable to allow imports or exports of research related data with the consent of the partner country that owns the data, if that promotes the effective collaboration between both parties and their mutual benefit.

The project partners take ethical rules very seriously and have high awareness of the importance of the values for respecting and protecting ethics regulations that apply in the non-EU partner countries. The project partners agree that it will be of high importance that the Early-Stage Researchers (ESRs) will also learn how to follow ethical guidelines and rules for respecting ethics requirements of research participants of the non-EU countries, if any.

Due to the nature of the research activities to be performed, **ethically relevant incidental findings are not expected in what concerns potential activities in non-EU countries.**



8 Ethics requirements in relation to the application of Artificial Intelligence

According to the EU AI Act (12), an Artificial Intelligence System is defined as “*A machine-based system designed to operate with varying levels of autonomy and that may exhibit adaptiveness after deployment and that, for explicit or implicit objectives, infers, from the input it receives, how to generate outputs such as predictions, content, recommendations, or decisions that can influence physical or virtual environments*”. According to that definition, the AI-based process quality monitoring system to be developed in STEEL-ALIVE can be considered an AI System because of its capability to predict the presence of certain defects in welded joints. As such, it must comply with the AI Act obligations. To determine the extent of such obligations, the EU has put in place an interactive assessment tool¹ that supports entities to identify their obligations.

The first step in the assessment tool is to determine which kind of entity is the organization leading the AI System, in STEEL-ALIVE’s case, CIDAUT. There are different roles considered in the Act, which are described below:

- **Provider:** a natural or legal person, public authority, agency or other body that develops an AI system or a general-purpose AI model (or that has an AI system or a general-purpose AI model developed) and places them on the market or puts the system into service under its own name or trademark, whether for payment or free of charge.
- **Deployer:** any natural or legal person, public authority, agency or other body using an AI system under its authority except where the AI system is used in the course of a personal non-professional activity.
- **Distributor:** any natural or legal person in the supply chain, other than the provider or the importer, that makes an AI system available on the Union market.
- **Importer:** any natural or legal person located or established in the Union that places on the market an AI system that bears the name or trademark of a natural or legal person established outside the Union.
- **Authorised representative:** any natural or legal person located or established in the Union who has received and accepted a written mandate from a provider of an AI system or a general-purpose AI model to, respectively, perform and carry out on its behalf the obligations and procedures established by the Regulation.
- **Product manufacturer:** places on the market or puts into service an AI system together with their product and under their own name or trademark.

According to these definitions, the role of STEEL-ALIVE, and CIDAUT in particular, in what concerns the development and implementation of AI Systems is **DEPLOYER**.

¹ <https://artificialintelligenceact.eu/assessment/eu-ai-act-compliance-checker/>



Regarding the modifications to be performed on the AI Systems, all developments foreseen consist in employing existing tools and algorithms but adapting them for the purposes of weld quality monitoring. In this sense, according to the AI Act prescriptions, the objective of the development would be to modify the intended purpose of a system already in operation.

The AI system does not fall within any of the high-risk categories detailed in Annex 1, Section B of the AI Act (Civil aviation security, two- or three-wheel vehicles and quadricycles, agricultural and forestry vehicles, marine equipment, interoperability of the rail systems, motor vehicles and their trailers, , and civil aviation), nor in any high-risk categories detailed in Annex 1, Section A (machinery, toys, recreational craft and personal watercraft, lifts and safety components of lifts, equipment and protective systems intended for use in potentially explosive atmospheres, radio equipment, pressure equipment, cableway installations, personal protective equipment, appliances burning gaseous fuels, medical devices, in-vitro diagnostic medical devices), nor in any high-risk categories detailed in Annex III (biometrics, critical infrastructure, educational and vocational training, employment, workers management, access to self-employment, access to and enjoyment of essential private services and public services and benefits, law enforcement, migration, asylum, border control management, administration of justice and democratic processes). For the sake of clarification, although the AI system will be applied in a production system, and in this regard, it will be to some extent linked to the machinery employed therein, it is believed that the AI system does not alter the behaviour of the production equipment itself, and therefore the high-risk category “Machinery” is not applicable. Also, it does not perform any of the prohibited functions as per the AI Act (subliminal techniques, manipulation, deception, exploiting vulnerabilities, biometric categorisation, social scoring, predictive policing, expanding facial recognition databases, emotion recognition in the workplace or educational institutions, real-time remote biometrics).

The AI System to be developed can be considered transparent, in the sense that it does not perform any of the following functions specified in the AI Act:

- Generating synthetic audio, image, video or text content
- Emotion recognition or biometric categorisation
- Generating or manipulating image, audio or video content constituting a deep fake
- Generating or manipulating text which is published to inform the public on matters of public interest.

It is important to remark that although the intention of STEEL-ALIVE is to align as much as possible with the AI Act considerations, its **actions are excluded from the AI Act Regulation according to Article 2 of the AI act, as they involve research and development activities prior to them being placed on the market or put into service.**

STEEL-ALIVE is also committed to the AI literacy obligations specified in Article 4 of the AI Act, and as such the partners involved in the development of the models will ensure a sufficient level of AI literacy for the staff and other people dealing with the operation and use of AI systems,



taking into account their technical knowledge, experience, education and training, and the context the AI systems are to be used in.

STEEL-ALIVE will also follow the recommendations included in the guide “Ethics by Design and Ethics of Use Approaches for Artificial Intelligence” (13), and will adhere to the six general ethical principles mentioned in the guide, which are:

- Respect for Human Agency: human beings must be respected to make their own decisions and carry out their own actions. Respect for human agency encapsulates three more specific principles, which define fundamental human rights: autonomy, dignity and freedom.
- Privacy and Data governance: people have the right to privacy and data protection, and these should be always respected.
- Fairness: people should be given equal rights and opportunities and should not be advantaged or disadvantaged undeservedly.
- Individual, Social and Environmental Well-being: AI systems should contribute to, and not harm, individual, social and environmental wellbeing.
- Transparency: the purpose, inputs and operations of AI programs should be knowable and understandable to its stakeholders.
- Accountability and Oversight: humans should be able to understand, supervise and control the design and operation of AI based systems, and the actors involved in their development or operation should take responsibility for the way that these applications function and for the resulting consequences.

9 Conclusions

This report describes the main ethical guidelines that need to be followed throughout the STEEL-ALIVE project’s lifetime. All ethical requirements and considerations included in this report are well aligned with the most recent European legislations and directives on the subject, and also with the Horizon Europe rules and recommendations on ethical issues, including data protection. The ethical requirements raised by STEEL-ALIVE will ensure that all the activities of the project are compliant with the highest ethical standards of the EC. Although no severe ethical issues have been identified during the self-assessment process, and no major changes to this initial scenario are expected during the project execution, the Consortium, and especially the Coordinator, will carry out a periodic re-evaluation to make sure that no ethically concerning matters appear, especially in what concerns misuse and Artificial Intelligence, because of the nature of the activities to be carried out within STEEL-ALIVE.



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