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D7.7 – Ethics guidelines

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Glossary of terms

Item	Description
DMP	Data Management Plan
PSC	Project Scientific Coordinator
GDPR	General Data Protection Regulation
TL	Task Leader
WPL	Work Package Leader
EAB	External Advisory Board
EC	European Commission
EU	European Union
H2020	Horizon 2020 Framework Programme
EM	Ethics Manager
FAIR	Fundable, Accessible, Interoperable, and Reusable
GA	Grant Agreement. The GA acronym is used in other project deliverables to indicate the General Assembly. In the present D7.7 deliverable, GA means Grant Agreement, while General Assembly is indicated in full
KOM	Kick-off-meeting
UN	United Nations
MOOC	Massive open online course
STEM	Science, Technology, Engineering e Mathematics
ICT	Information and Communication Technologies
AI	Artificial Intelligence
ML	Machine Learning

Keywords

Artificial Intelligence; Edge Computing; Computing Continuum; Ethics; Ethics management; Data protection and privacy; Gender balance; Informed consent.

Disclaimer

Executive Summary

The project activities are not likely to raise ethics issues, as indicated in the Annex I of the Grant Agreement. No clinical trials are foreseen, and project activities do not raise concerns of dual use. However, AI-SPRINT is a collaborative research project that involves several researchers and stakeholders, and therefore scientific and personal data will be collected. Furthermore, three pilots will be implemented in the project, one of them being focused on personalised medicine, where data on patients and volunteers will be collected and elaborated. A guide that highlights ethics-related issues and how to address them is therefore necessary to help researchers abide by the key principles of ethics in research and for improving the quality of research outcome [Hughes2010].

The present deliverable D7.7 *Ethics guidelines* aims to guide the research activities of the H2020 AI-SPRINT project in respecting key ethical research principles as well as to improve the soundness and quality of the project results. The document provides a description of the key ethics principles that guide the execution of the project, the process for monitoring and managing ethical issues, as well as the organisational structure and the tools that will be used. The document recalls the obligations related to ethics and research integrity set in the Grant Agreement and additional ethics principles, such as data management and privacy, gender balance, and informed consent when human beings are involved, that are of paramount importance in research. For each principle, the approach that will be adopted and the actions that will be performed by the partners to abide are indicated. Furthermore, a process for identifying ethics-related issues and managing them is proposed. The process is based on a distributed responsibility where actors, working on the project at the different levels, will be informed about the issues and will be responsible for highlighting the emergence of issues, discussing them with the necessary coordinator (e.g. Task leader, WP leader, Ethics manager), who will suggest the actions to be undertaken. In case issues cannot be managed at the level they are identified, an escalation process foresees the involvement of the Project Scientific Coordinator, the External Advisory Board, the General Assembly, the European Commission.

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1. General principles of Ethics Management in the AI-SPRINT project

The first chapter of this deliverable introduces the relevance of ethics in research (Section 1.1) and highlights the key ethics principles that should inspire research in general and the AI-SPRINT project in particular (Section 1.2). Application of the guideline and liability are also indicated (Section 1.3).

1.1 Locating ethics in the AI-SPRINT project

Ethical issues are of paramount importance to research, innovation, science, and technology [Wolfensberger1967, Hughes2010]. Research can be defined as the "aim to generate (new) information, know- ledge, understanding, or some other relevant cognitive good, and does so by means of a systematic investigation [Hughes2010, p. 14]. The definition incorporates some key aspects such as a systematic investigation to find out something new, the aim of developing generalisable knowledge, a systematic investigation targeting the generation of scientific knowledge and understanding, the collection of data on a specific phenomenon or subject, the search for evidence. An unavoidable and fundamental aspect of research is therefore uncertainty, which characterises the outcome of the research activities, the potential benefits, and the risks involved. Furthermore, research is a collaborative action, where researchers and stakeholders collaborate in the generation of new knowledge. All these aspects can raise ethical challenges and research that is carried out without clear guidelines is doomed to cope with ethical issues or even lead to ethical issues, violation of ethical principles, violation of agreements, national and international regulations, and even scandals.

High ethics standards also add to the quality of research and increase its social impact, promoting better alignment or research to social needs and expectations, which is crucial to tackle the challenges that European society confronts. Ethics assessment of innovation enables the characterisation of the ethical dimensions of new technologies and applications, which, in turn, allows us to make informed decisions about which technologies to promote, which to discourage and how to develop and distribute them in just and ecologically sensitive ways.

In the context of the present document, "Ethics" is defined as the "norms for conduct that distinguish between acceptable and unacceptable behaviour"[1]. Ethics is closely connected with the partnership's duties and responsibilities towards other individuals and to the society as a whole and refers to the respect of their dignity and rights, ensuring their well-being and avoiding harm. Moral values and principles that are often referred to in ethics include justice, freedom, autonomy, privacy, dignity, well-being, and responsibility.

1.2 Key Ethics Principles that underpin research in AI-SPRINT

The execution of the AI-SPRINT project will adhere to a set of ethical principles. Three types of principles have been considered: (1) ethics principles mentioned in the Grant Agreement (GA); (2) general ethics principles that should inspire research and aimed at guaranteeing respect of human rights and balance of benefits and harms; and (3) specific principles related to data protection and privacy, gender balance, and informed consent. In addition, since AI-SPRINT is a collaborative project that involves different countries and regulations, all project partners must adhere to specific provisions of the international and national regulations (as also mentioned in the Grant Agreement). The key principles are described in the following paragraphs. To be noted that the mentioned principles exhibit some degree of overlapping. Principles such as research integrity, compliance with regulations, data protection and privacy are recurrent issues in different principles.

[1] www.niehs.nih.gov/

1.2.1 Ethics principles foreseen in the Grant Agreement

Ethics and Research Integrity is regulated by Art. 34 of the project Grant Agreement. The article recalls the need of the partners to comply with ethical principles (including the highest standards of research integrity) and the applicable international and national law. Furthermore, the article recalls that the research activity funded by the European Commission should be focused on civil application (no dual use is accepted). Finally, in relation to embryos, research should not address cloning, modification of genetic heritage, and creation of human embryos for the purpose of research or for the purpose of stem cell procurement.

In relation to research integrity, the key principles of the European Code of Conduct for Research Integrity must be respected:

- 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 organisation, for training, supervision and mentoring, and for its wider impacts.

Inspired by these principles, the European Code suggests some good practices that should guide research, such as the following.

- Research environment. Integrity should be a common trait in all activities performed by research institutions and organisations participating in research.
- Training, supervision, and monitoring. Organisations should ensure that all participants in a research-oriented activity will receive adequate training in research design, methodology and analysis.
- Research procedures. Specific procedures related to the consideration of the state of the art in developing research ideas, research design, proper use of public funds, publication of results in an “open, honest, transparent and accurate manner”, and respect of confidentiality of data.
- Safeguards. Researchers should follow codes and regulations relevant to their discipline. Research should be carried out with respect and care, and in accordance with legal and ethical provisions. Researchers should also have due regard for the health, safety, and welfare of the community, of their collaborators and other stakeholders connected with their research.
- Data protection and management. Researchers and organisations involved in research must exhibit proper curation of all data and research materials, including unpublished ones. Management of data should follow a FAIR (Findable, Accessible, Interoperable and Re-usable) principle, as also required in the indications for the preparation of the project Data Management Plan.
- Collaborative working. Collaborative projects involve different organisations and researchers who take responsibility for the integrity of the research carried out. All organisations and researchers agree on expectations and standards on research integrity. All researchers should be properly informed and consulted about submission for publications or presentations of research results.
- Publication and dissemination. All authors are responsible for the contents of the publications.

As foreseen in Art. 34.2 of the Grant Agreement, before starting an activity that can potentially raise an ethical issue, each beneficiary initiating the activity must have obtained (a) the opinion of an ethics committee and (b) the notification or authorisation for activities raising ethical issues required under national and/or European law.

It is to be noted that all AI-SPRINT partners agreed on the presence of no critical activities raising ethical issues during the preparation of the project proposal, as foreseen in the Annex I of the Grant Agreement.

Nevertheless, the project partners will entail all actions and measures to prevent, monitor, and mitigate any ethical issues that may arise during the execution of the project activities.

1.2.2 General ethics principles

The execution of the AI-SPRINT project will adhere to general principles aimed at guaranteeing respect of human rights, including compliance to personal data regulations, and the balance of benefits and harms.

Concerning the respect of human rights, the Universal Declaration of Human Rights[2] recalls the individual rights and freedoms deserving respect, such as freedom of movement, of assembly, of speech and expression, autonomy, human dignity, bodily integrity, privacy and property. Any activity, including research, must comply with the same principles. In relation to research funded in the framework of the Horizon2020 Programme, ethics is given high priority. In the context of research activity funded by the EU, the Lisbon Treaty[3] makes explicit reference to the Charter of Fundamental Rights of the European Union[4] which underlines the right to the integrity of a person, the respect for private and family life, the protection of personal data, as well as the freedom of the arts and sciences. In addition to that, the Treaty on the Functioning of the European Union[5] (Art. 16) recall the right to protect personal data. The GDPR regulation[6] was issued by the European Parliament and the European Council in 2016 to protect natural persons with regard to the processing of personal data and on the free movement of such data.

Ethical research should balance benefits and harms. Each research activity involving human beings, either as participants or as subject of the investigation, involves some "burden or costs, such as the risk of physical or other harm, inconvenience, sacrifice of time or monetary expense" [Hughes2010, p.95]. The justification of these costs is based on the evidence of the corresponding benefits. Three types of benefits connected to research can be identified in research ethics literature. First, research may bring benefits to the subjects participating in the study. The adoption of remote monitoring systems, such as those connected to ambient assisted living, for instance may improve the safety and the quality of life of the elderly. In this case, an ethical approach to research requires clear identification of the population that can benefit from research and a sound analysis of the factors that influence the link between research and the outcomes. Generalisability of results is necessary to demonstrate that the benefits for a wide population exceed the costs of the study. Second, research may lead to benefits to future participants. For instance, the analysis of the effect of some new medicines on patients may be useful for identifying a cure to some illnesses and future patients will benefit from it. Researchers may not know in advance the outcome of their research and the potential benefits may be unknown during tests. However, results may inform future research that will bring new treatments and medicines. Rigorous measures to carry out research, assessing and monitoring negative consequences, as well as identifying and estimating the potential benefits are necessary requirements for ethical research. Third, research may provide intellectual, financial, reputational benefits to the research organisations involved in the investigation and to researchers. This rationale is based on the assumption that the increased intellectual, financial, reputational condition of organisations and researchers will be used for public interest. In this case, a clear identification of the core activities carried out by organisations and researchers to show evidence of the public interest is necessary to overcome the concern that research is carried out for unethical purposes, such as money or prestige. In order to balance benefits and harms, it is necessary for researchers to keep track of the harms generated by the study, of the benefits, directly produced by the study to the participants or that can tackle future participants, of the characteristics and size of the populations that can potentially benefit from research results.

[2] ONCHR https://www.un.org/en/about-us/universal-declaration-of-human-rights
[3] The treaty is available at: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A12007L%2FTXT
[4] The Charter is available at: http://www.europarl.europa.eu/charter/pdf/text_en.pdf
[5] The treaty is available at: https://eur-lex.europa.eu/resource.html?uri=cellar:41f89a28-1fc6-4c92-b1c8-03327d1b1ecc.0007.02/DOC_1&format=PDF
[6] The regulation is available at: https://eur-lex.europa.eu/eli/reg/2016/679/oj

1.2.3 Specific Ethics principles in the AI-SPRINT project

In addition to the ethics principles contained in the Grant Agreement of the AI-SPRINT project and to the general principles derived from EU regulations, the project must comply with specific principles such as data management and privacy, gender balance, and the involvement of personnel and stakeholders who have provided an informed consent.

In 2018, the General Data Protection Regulation (GDPR Regulation) replaced the Directive 95/46 on data protection and currently is the main EU legal act regulating the protection of personal data in all Member States of the European Union. The Regulation applies to all entities established in the EU (or branches established in the EU) that process personal data as part of their activities, regardless of where the data is processed; and entities established outside the EU, offering goods/services to individuals in the EU or monitoring the behaviour in the EU of these individuals. According to GDPR, personal data indicates "any information relating to an identified or identifiable natural person ("data subject"); an identifiable natural person is one who can be identified, directly or indirectly, in particular by reference to an identifier such as a name, an identification number, location data, an online identifier or to one or more factors specific to the physical, physiological, genetic, mental, economic, cultural or social identity of that natural person". Processing of personal data is defined as "any operation or set of operations which is performed on personal data or on sets of personal data, whether or not by automated means, such as collection, recording, organisation, structuring, storage, adaptation or alteration, retrieval, consultation, use, disclosure by transmission, dissemination or otherwise making available, alignment or combination, restriction, erasure or destruction".

The gender balance principle addresses the importance of taking an inclusive and participatory approach to address gender inequalities in all phases of the research project. This consideration tackles the activities implemented during research and the outcomes of research. During research activities, the general ethical research approach foresees campaigns addressed to female stakeholders to guarantee an equal participation of gender at any research activities, workshops, as well as dissemination and communication initiatives and events. As for the research outcomes, it is imperative to be aware of the existence of biases (e.g., the digital divide in the access/use of the technologies between men and women) and true differences (e.g., plenty of sex differences reported for many diseases). Researchers must be carried out in a way to reduce the effect of biases and of differences. Furthermore, project results are not foreseen to affect women and men differently and all the outputs are expected to be non-gendered [Tannenbaum2019]. Partners will incorporate sex and gender analysis into research and innovation content and management activities to ensure that the sex and gender dimensions are properly considered, removing potential barriers to adoption and take-up.

Whenever human beings are involved in research, both as researchers and as the subject of research, the informed consent principle requires that all participants are properly informed about the type of research they are involved in, the potential risks, and how data will be collected, shared and used. Informed consent is implemented through clear elucidation of the activities. Members of the study team provide any necessary clarification and answer any potential questions that the participants may have. Regulations and policy require that certain information is provided as part of the consent process. The language of the illustration should be aligned with the skills and knowledge of the participants. Main aspects of informed consent comprise: (1) the potential participant must be given adequate information to be able to make a choice about whether or not to share its information that is based on an understanding of the risks and alternatives in an environment, which is free from any coercion; and (2) the decision of the potential participant on the consent issue must be evidenced. An informed consent document is typically used to provide subjects with the information they need to decide to participate in the research activity. The informed consent document is designed to be clear and straightforward, aimed at ensuring the participants understand and agree to participate.

1.3 Application boundary of the document and liability of project partners

D7.7 provides guidance on how research in the AI-SPRINT project will be carried out in order to comply with necessary ethics principles. Guidelines apply to all actors involved in the project, such as researchers and stakeholders (e.g., actors participating in the pilots). While researchers will be properly informed about the ethics requirements (as detailed in the rest of the document), stakeholders will have to be properly informed. It's the responsibility of the project researchers to provide the necessary information on ethics requirements to all actors involved in the project. In the present deliverable, different resources are described that can be used to raise awareness about ethics requirements. They comprise for instance documentation on ethics in research, webinars, and questionnaires. These resources can be made available to all actors involved in the project.

The present document offers a set of resources, processes, and suggestions on how to prevent ethics issues to emerge in the execution of the AI-SPRINT project. While all participants in the project are invited to raise awareness on ethics requirements and to apply measures to prevent any ethics issues to emerge or take actions to mitigate their effects, application of ethics principles in research is under the responsibility of each partner. All partners are liable for all breaches related to ethics problems they might have contributed to generate.

1.4 Structure of the document

The present D7.7 on ethics management is organised as follows. After the introductory Chapter 1 that recalls the general ethics principles that research should comply with, in Chapter 2, the process for guaranteeing the adherence to the ethics principles is described. Chapter 3 recalls the provisions for the execution of the specific principles. Conclusions are finally drawn in Chapter 4.

2. The Ethics management process

The second chapter of this deliverable highlights the key organisational bodies of the AI-SPRINT project that contribute to the implementation of ethics principles (Section 2.1) and to the procedures designed to guarantee that the project execution complies with the ethics principles described in Chapter 1 (Section 2.2).

2.1 Ethics management and organisational bodies

The project management structure of the AI-SPRINT project is part of the Grant Agreement and was detailed in D7.1 Project management plan. The structure foresees a set of organisational bodies that are responsible for the execution, coordination, monitoring and supervision of the project activities. In particular, in relation to the ethics issues, it is to be noted that:

- The General Assembly is the highest decision body of the project and supervises and makes decisions on key issues of the project. In case of ethics issues that deserve the highest attention, the General Assembly will be consulted and will have to make decisions.
- The Project Scientific Coordinator (Danilo Ardagna) supervises and coordinates all scientific activities of the project, including ethics issues.
- Research activities are carried out in the framework of 7 WPs, split into Tasks. Each WP and Task is coordinated by a WP and a Task leader respectively. As described in the following section, WP leaders and Task leaders will be consulted in case any ethics issues will be identified in the execution of the project. Based on the gravity of the issues, they may contact the PSC.
- In their activity, the PSC is supported by a Scientific Director (Rosa Badia) who will focus on scientific aspects of the project and will help the partners carry out research consistently with the aim of a highly ambitious and innovative project, and by some supporting roles, among whom an Ethics Manager (Fabrizio Amarilli). The EM will be responsible for defining the Ethics procedures of the project, in accordance with the project partners, and of monitoring the application of the ethics principles. The EM will also suggest measures to mitigate effects of ethics issues and how to inform and interact with the other organisational bodies.
- The External Advisory Board is a consulting body composed of scientists and professionals in the domain of AI, Cloud, and Edge technologies, as well as in their application to different domains. The experts are consulted regularly throughout the project implementation to provide guide and opinions on specific issues. They may be also consulted in case some ethics issues emerge.

All organisational bodies are informed about and aware of the ethics issues of the AI-SPRINT project (described in Chapter 1) and will participate in the ethics principles implementation. All AI-SPRINT partners have previous experience in participation in EU funded research projects and are familiar with the ethics issues and the principles highlighted in the present deliverable. In addition to that, the principles have been re-stated during the project Kick-off meeting (when the Ethics Manager was also appointed) and recalled during project coordination meetings.

In addition to the organisational bodies foreseen in the project, some partners can rely on internal or external Ethical committees that may be involved in case of need. Within the coordinator, POLIMI, an ethical committee offers support to POLIMI scientists and researchers involved in research project, to the structures directly affected and to the POLIMI management bodies to ensure that “research takes place in accordance with the ethical principles defined by international and Italian legislation and by the University's Ethics Code”.[7] The committee is composed of experts who are internal and external to the university and can be involved for consultancy on an “on-demand” form in case a research project requires their support.

[7] https://www.polimi.it/en/scientific-research/contacts/ethical-committee/

2.2 Ethics management process

The process for managing ethics issues in AI-SPRINT follows a distributed- and escalation- based approach. This approach is translated into three types of practices that guide the ethics management in the project (Fig. 2.1): (1) raising awareness on ethics requirements, (2) monitoring, and (3) resolution of problems or mitigation of effects.

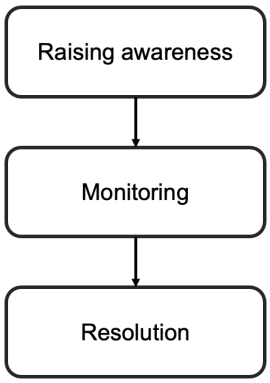

Figure 2.1 – Ethics management practices in AI-SPRINT

2.2.1 Practices for raising awareness on ethics requirements

Several practices have been and are being adopted to guarantee that all actors involved in the project are aware of the ethics issues. Even though most partners are already familiar with the requirements of research ethics (most universities foresees courses on ethics under PhD programmes), the consortium has decided to undertake different actions to maximise the participants knowledge on the topic.

The practices foreseen to raise awareness are the following:

- Presentation during the Kick-off-meeting. The key ethics principles in research, the need to adhere to them, and the provisions related to ethics contained in the GA were recalled during the Kick-off-meeting. The role and responsibilities of the different organisational bodies, including the responsibilities related to ethics management, were underlined. During the meeting, the Ethics Manager has also been appointed.
- Preparation of the present deliverable. During the preparation of D7.7, its contents were shared, revised, and agreed by project partners. All partners should therefore be sufficiently sensitised to the need to comply with ethics principles. Nevertheless, AI-SPRINT is a three-year project, and it is plausible that new researchers and non-scientific staff will be involved during the implementation of the project. Furthermore, external actors, such as those involved in the implementation of the pilots, may start collaborating and contributing to the project in a subsequent phase. Therefore, additional actions are required.
- Online workshop on ethics management. During the implementation of the project, a workshop will be organised to discuss the topic of ethics management. The workshop will be organised by the project coordinator and managed by the Ethics manager and will address the following specific issues: the risks connected to unethical research, the key principles of ethics research, practices for managing ethics in research, specific topics related to data management and informed consent. The workshop will be delivered online and will be recorded so that new participants may have the possibility to access the contents.

- Repository of resources. Within the online repository that is used by the project partners to coordinate activities, collaborate on documents, and share data, a folder[8] has been dedicated to ethics resources. The folder is accessible to all partners and contains resources such as the European Textbook on Ethics in Research [Hughes2010], the European Code of Conduct for Research Integrity [ALLEA2017], the United Nations Corporate Responsibility to Respect Human Rights guide [UN2012], the Universal Declaration of Human Rights, the Early-career researchers' views on ethical dimensions of patient engagement in research [Belisle2018].
- List of online open resources. The topic of ethics in research has drawn the attention of several research institutions, who have included it in their institutional programmes. Therefore several resources are now available. Annex VI provides a list of the courses that can be attended online. All courses mentioned are provided in a MOOC form.
- Dedicated sessions during consortium meetings. Beside the KOM, During the implementation of the project general coordination meetings are foreseen. A session dedicated to recalling the key ethics requirements and for discussing actions undertaken by the partners to raise awareness and prevent ethics issues from emerging will be organised. The session will be managed by the EM.

In addition to the practices to raise awareness, a survey will be conducted to assess the current knowledge of the partners on ethics aspects and the organisational readiness to address them. Aspects that will be assessed include the presence of an ethics committee, the adoption of ethics practices in job procedures, the presence of ethics articles in job contracts, the introduction of ethics topics in the training programs of researchers and non-researching staff. The candidate questionnaire for the survey is included in Annex IV.

2.2.2 Practices for monitoring ethics management

During the implementation of the project, partners will properly monitor the compliance of the activities with ethics principles. In order to pursue this objective, the following practices have been adopted:

- Reviewers' checklist. The designed quality procedures for the preparation of the project deliverables foresee an internal peer review process. In addition to quality check, reviewers will be also invited to highlight any ethical issues that might be connected to the activity that led to the preparation of the deliverables. The checklist will suggest reviewers to highlight aspects such as the presence and the types of data collected from users, the process for guaranteeing anonymity of data, the storing process of data, the involvement of end users in the activities, the gender balance aspect in the involvement of personnel, the existence of biases and true differences in the outcomes of the activities. Annex V provides a list of questions that will be used by the deliverables' reviewers as a checklist on ethics issues.
- Project partners have agreed on a strict coordination approach that foresees frequent coordination meetings. During the first year of activity, in addition to the KOM and a consortium meeting, bimonthly meetings have been organised. During the meetings, a room was reserved to check and discuss ethics issues. At the end of the first year of activity, no ethics issues have been highlighted by the participants. The same approach will be adopted in the coordination meetings in the second and third year of activity.
- During the implementation of the project pilots, based on the provisions of Art. 34.2 of the GA, the corresponding Task leader will be responsible for presenting the pilot activities to the PSC and to the EM and to justify the need of an ethics committee opinion or authorisation. In case they are needed, the partner responsible for the pilot will implement all the necessary actions to gather the opinion or authorisation. In case of need, the Ethics committee that is present at POLIMI can be consulted.

[8] The folder is available at the link:
https://drive.google.com/drive/folders/1HbKyx6ulC3L1y12cL0DTu2mt8Wqxv991?usp=sharing

2.2.3 Practices for making decisions and resolving ethical issues

The ethics management process of the AI-SPRINT project foresees a distributed approach in the identification of ethics issues. All actors participating in the project activities will be responsible for raising objections in case potential ethics issues are identified. The decision-making process and the resolution process will follow an escalation approach where the decision makers and the actuators will depend on the type and gravity of the ethics issue identified.

In case an issue connected to any ethics principle will emerge during the execution of the activities, the involved actor identifying the issue will have to inform the appropriate organisational bodies to share the issue and agree, if necessary, on appropriate actions. The organisational bodies to be informed and to be involved depend on the type of issue and on the gravity. The EAB or the EC can be consulted if needed. Three levels of gravity have been identified and the corresponding processes are exhibited in the Table 2.1.

Gravity	Example	Who detects	Who is informed	Who takes decisions	Who is consulted (optional)
Low	Partners' ethics questionnaire is filled in with delay	Any participants' actor	Task leader, WP leader, EM	WP leader	
Medium	The process for hiring new personnel is outsourced and the partner has no visibility on the gender balance approach adopted.	Any participants' actor	Task leader, WP leader, EM, PSC	PSC	EAB, Ethical committees
High	A breach of confidentiality is highlighted in the process of sharing project data	Any participants' actor	Task leader, WP leader, EM, PSC, General Assembly	General Assembly	EAB, EC, Ethical committees

Table 2.1 - Gravity of ethics issues and corresponding decision-making processes

The actions to resolve an issue that is identified are defined based on an escalation process. The actor raising an ethics concern will consult the Task leader and the WP leader and, based on the issue's gravity, inform the EM, the PSC, and the General Assembly. The Ethics manager will suggest on how to proceed. The issue may be addressed by the partners in the context of the Task or WP activities or require a higher-level decision-making process. In case of issues of medium and high gravity, the emergence of the issue and the actions suggested will be shared with all partners during the periodic coordination meetings of the project. In case the issue cannot be solved by the intervention of the Ethics manager and the WP and Task leader, the PSC will be informed and together with the Ethics manager he will decide whether the support of additional bodies, such as the EAB, an ethical committee, and ultimately the EC will be required. Based on the Task connected to the issue, PSC and EM will also define which body will be consulted and which Ethics committee will be contacted (e.g. in case an issue will emerge during the execution of a pilot, the ethics committee, if present, of the partner coordinating the pilot could be primarily involved). In this case, the EM and the PSC will contact the consulting body for the required suggestions (the EM will contact the Ethics committees, the PSC will contact the EAB and the EC). Suggestions proposed by the bodies consulted will be shared with all

partners, decisions, if necessary, taken, and the required actions will be undertaken. Results and efficacy of the actions will likewise be shared with all partners. Only in case no results are achieved, the General Assembly will be consulted.

The Ethics Manager will track all the ethics issues that emerged during the execution of the project, the decision-making process, the consultancy activity, the actions, and the results. All data will be included in the progress report and in the periodic interim and final reports of the project.

3. The Ethics management in AI-SPRINT

In the following chapter we highlight the provisions for addressing the specific ethics principles related to data management and privacy (Section 3.1), the gender balance (Section 3.2), and the informed consent (Section 3.3).

3.1 Data protection and management in AI-SPRINT

AI-SPRINT is a collaborative research project. All activities of the project therefore foresee the collection and elaboration of data and the participation of researchers and external actors. In addition to that, during pilots' execution, data from stakeholders directly involved in the pilots will be collected.

The AI-SPRINT project pursues a 'privacy by design' approach to guarantee that all research activities are performed in compliance with ethics principles. The project will enable mechanisms to avoid any intentional or unintentional use of information that can bring any harm to any participant or being misused in other contexts. All partners will act according to national and European legislation, in line with national data protection provisions and the European data protection rules (GDPR). The participants will also implement specific provisions when recording, analysing, and storing data, as highlighted in D7.3 Data Management Plan. Each partner is responsible for compliance in their country and must be able to justify it and prove it to the ethical committee as well as observe national and EU legislation.

Different types of data will be collected during the execution of the AI-SPRINT project, encompassing research and technical data, data on participants to the project, data of the stakeholders who will contribute to the activities and to the dissemination and exploitation of project results, visitors to the events where the project results will be showcased. Furthermore, data will be collected through the project website. Data management in the project will guarantee that collected data through the engagement activities and the project website will strictly comply with Council of Europe – Convention for the Protection of Individuals with regard to Automatic Processing of Personal Data, of January 28th 1981 and will verify possible contributions to the open research data, open EC database and possible contributions to open knowledge repositories. The project collection of data will also comply with the GDPR Regulation.

Researchers will guarantee the anonymity of the interviewed people throughout the research activities and keep completely anonymous any information that interviewees wish to hide for reasons of personal safety or privacy. The procedures the partners will implement for the collection, storage, protection, retention, and destruction of data comply with national and EU legislation.

3.2 Gender balance in AI-SPRINT

Due to the complexity of the project, different male and female participants will contribute in different forms to the project. Scientists and researchers will carry out research activities, novel researchers, such as early stage researchers or Phds may be hired or involved, civil society will take part to public events and will be informed of the project results, the scientific community will get in contact through different dissemination channels with the project results, different stakeholders such as the personalised healthcare volunteers will actively contribute to the execution of the activities.

Project partners will take all measures to promote and provide equal opportunities between men and women, and secure gender balance at all levels of the project and in all activities. This gender dimension is considered and integrated in the entire research process. However, based on previous research experiences, integrating the gender perspective is not an easy task because it must be applied in a structural way and adapted in the different steps of the research.

In the composition of research groups and of organisational bodies, the project will try to balance the composition of women and men of each team; the decision-making process will prioritise the existence of a

shared leadership between women and men (the principle was applied from the early stage of the project, when the research idea was conceived, and Danilo Ardagna was appointed PSC while Rosa Badia was appointed as Scientific Director); there will be measures to assess that the gender perspective will be applied in the process; during recruiting phase of researchers (e.g. in case of early stage researchers and PhD students) gender balance will be applied; if necessary, the dissemination of research will emphasise how the gender dimension has been included throughout the process, serving as a demonstration effect for other research projects.

Gender balance will also be addressed in the analysis of the research data, in order to avoid gender-related biases. Whenever data is elaborated to produce results, researchers will be invited to also take a gender-lens to identify potential biases. Deliverables' reviewers are also invited to monitor and highlight this risk when analysing results included in the deliverables. In case any issue will emerge, the EM and the PSC will be informed, and the appropriate actions will be defined.

3.3 Informed consent in AI-SPRINT

Informing participants and stakeholders of the activities undertaken, of the potential risks and consequences of the participation, of the data collected and of their elaboration and use is required in all project activities and, in particular, during the pilots' execution. The project foresees three pilots, Farming 4.0 focused on the optimisation of phytosanitary products used in vineyards; Maintenance and Inspection where AI models will be used to identify windmill blade damage based on vision and thermal images collected by drones; and Personalised Healthcare focused on the development of an automated system for personalised stroke risk assessment and prevention based on continuous and non-invasive monitoring of heart activity. Beside the maintenance and inspection pilot, where the subject of data collection and the tools for collecting data are not related to human beings, the other pilot will foresee the active participation of personnel.

All participants to the project, at all levels (e.g., researchers, pilots' participants, informants, project stakeholders), will be asked to provide an informed consent form that must be signed by the members of the project researchers. Consent must be obtained before participation in the activities. Before collecting the informed consent, participants will receive information about the project aims, expected results and limits of the research. The purpose is to ensure that participants fully understand the implications of being involved in the research. Participation in surveys, collection of data via the Website, interviews and questionnaires during events is voluntary and the participants will not be subject to any psychological, social, economic, or other form of risk. The content of the consent document will be translated in order to avoid misunderstanding with participants.

All participants will also be informed that they may withdraw from the research process during its data collection phase. If the research participant decides that they do not want to participate in the research process during the collection data phase, for any reason, they will be able to do it. In the informed consent document, there will also be information about the anonymization procedure that we are going to implement to guarantee the confidentiality of the data.

Children or adults unable to give their informed consent will never be selected as research participants. The consent of their legal representatives is very difficult to obtain. In addition, it is not necessary for this research to expose them to possible stress in the interviews. Therefore, their involvement is out of the scope of the research conducted in the AI-SPRINT project.

Preliminary versions of the informed consent documents for the participants in the pilot on personalised healthcare, for the volunteers and caregivers, have been prepared and are included as Annex I and Annex II.

4. Conclusions

This deliverable offers guidelines for addressing ethics in the execution of the AI-SPRINT project. The key principles that inspire ethical research and that must be monitored during the project implementation are related to the project Grant Agreement (in particular, Art. 34 on Ethics and research integrity), to the need of respecting human rights and the balance of benefits and harms, and to the management of data and privacy, the gender balance, and the informed consent of all participants. Ethics management is addressed in the AI-SPRINT through the identification of organisational bodies who contribute in different forms to the identification, monitoring, and decision making and through the definition of an ethics management process. The process is based on a distributed and escalation approach, where all actors participating in the project will be properly informed and trained on ethics issues. Actors will be responsible for identifying issues and, based on the type and gravity of the issues, inform the appropriate organisational bodies. For low gravity issues, decisions and actions might be taken at the Task or WP level. In case of issues of medium and high gravity, higher level organisational bodies will be involved in the decision-making process. If needed, some consulting bodies such as the EAB, the Ethics committees, and the EC can be involved.

A set of resources has been defined to address some specific issues that are peculiar to the project, such as data management and privacy, gender balance, and informed consent. All partners will comply with national and European legislation, in line with national data protection provisions and the European data protection rules (GDPR). The participants will also implement specific provisions when recording, analysing, and storing data, as highlighted in D7.3 Data Management Plan. Partners will take all measures to promote and provide equal opportunities between men and women, and secure gender balance at all levels of the project and in all activities. Gender balance will also be addressed in the analysis of the research data, in order to avoid gender-related biases. All actors participating in the project will be informed about the risks connected to the participation and about the type of data collected and how this will be elaborated and stored. An informed consent form will be used for all the actors involved in the implementation of the pilots, in particular in the Personalised Healthcare one.

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Annex I - Personalised Healthcare pilot, volunteers' recruitment

During the execution of the pilot Personalised Healthcare (WP5) volunteers will be invited to participate and their personal data, such as heart rhythms, atrial fibrillations, electrocardiograms, will be collected through a wearable device. Additionally, lifestyle information will be collected through a questionnaire about the neurovascular risk factors. The following form is the template prepared to illustrate to the participants the objective of the AI-SPRINT project, the activities, the potential risks, and the data collected. The form will be issued to the volunteers only after a verbal introduction to all key aspects of the project has been given. Volunteers will be free to choose whether to participate in the activities.

VOLUNTEER RECRUITMENT

The plan to recruit volunteers to participate in the Personalised Healthcare use case of the AI-SPRINT project, a Research and Innovation Action under the H2020 call on Cloud Computing (H2020 ICT-40-2020), coordinated by Politecnico di Milano, Italy, will be will design, work and execute with the collaboration of the "Freno al Ictus" Foundation, through a sub-contract in the framework of the project.

The steps we will follow for the recruitment of patients will be as described below:

- Before starting the pilot phase of the use case, a working group consisting of clinician, foundation staff and project partners will be set up to finalise all aspects of the pilot study design.
- Once these aspects have been confirmed, we will finish defining the characteristics of the volunteers who will participate in the study, both in the group of healthy people and in the group of people who have previously suffered a stroke.
- The recruitment phase will be in charge of "Freno al Ictus Foundation".
- Thanks to its social positioning and the close collaboration maintained with different stroke and acquired brain injury associations, the Foundation will have access to potential volunteers who will be invited to participate in the study.
- For the invitation to participate in the study, the Foundation will contact potential volunteers through different channels (will be defined in the following months), providing them with all the information about the project and its role.
- Those volunteers who finally decide to participate in the study will be coordinated, prepared and trained through face-to-face or virtual sessions. In this sense, the collaboration of the project partners will be also needed to explain the technical aspects of the wearable device.
- Once the volunteers have received all the necessary information, they will be provided with a patient information sheet containing every aspect of the study related to their participation, including the possible benefits and harms of participating in the study.
- Those patients who agree to participate must give written informed consent signed by them or by the caregivers responsible for their supervision.
- The "Freno al Ictus" Foundation will be responsible for collecting and anonymising all information concerning volunteers, in compliance with the current General *Data Protection Regulation* (EU) 2016/679 ("*GDPR*"). The Foundation will store all the sensible information in-house, with restricted access only to the members of the Foundation that will be responsible for the patient and data

management. The AI-SPRINT consortium will have access to the data collected and generated during the pilot only after the anonymization process is completed, that is all identifiers have been irreversibly removed and subjects are no longer identifiable in any way.

Annex II - Personalised Healthcare pilot, caregiver informed consent

In case of involvement of children or of patients unable to provide informed consent, information on the project will be provided to caregivers. The following form is the template prepared to illustrate to the caregivers the objective of the AI-SPRINT project, the activities, the potential risks, and the data collected. As for the volunteers, the form will be issued to the caregivers only after a verbal introduction to all key aspects of the project has been given.

CAREGIVER INFORMED CONSENT FOR THE AI-SPRINT RESEARCH PROJECT

Researcher / Clinician:
Title of the project: **AI-SPRINT PROJECT**

I (NAME AND SURNAME OF CAREGIVER):

As the patient's caregiver (Relation with the patient):

NAME and SURNAME of the patient:

- I have read the patient information sheet that has been given to me
- I was able to ask questions about the study
- I have received enough information about the study
- I have spoken with: (name of the researcher):

I understand that participation is voluntary and I understand that my family member can withdraw:

- Whenever the patient want
- Without having to explain
- Without this having repercussions on the patient's medical care

In my presence has been given to (name and surname of the participant):

- All relevant information adapted to the level of understanding of the participant and consent to participate in the study.

I freely give my consent for my family member to participate in the study.

Patient’s signature:
Data:

Caregiver’s signature:
Data:

Researcher’s Signature:
Data:

Annex III - Personalised Healthcare pilot, patients informed consent

During the execution of the pilot Personalised Healthcare (WP5) patients will be invited to participate and their personal data, such as heart rhythms, atrial fibrillations, electrocardiograms, will be collected through a wearable device. Additionally, lifestyle information will be collected through a questionnaire about the neurovascular risk factors. The following form is the template prepared to illustrate to the participants the objective of the AI-SPRINT project, the activities, the potential risks, and the data collected. The form will be issued to the patients only after a verbal introduction to all key aspects of the project has been given. Volunteers will be free to choose whether to participate in the activities.

PATIENT INFORMED CONSENT FOR THE AI-SPRINT RESEARCH PROJECT

Researcher / Clinician:
Title of the project: **AI-SPRINT project**

I ..... with DNI .... I declare that I have read the Patient Information Sheet, from which I have been given a copy. I have received information about the characteristics of the study, as well as the possible benefits and risks that I can expect, the rights I can exercise, and the provisions on the treatment of data. I have received enough information about the study.

I know that my identity will be kept secret and that my samples and data will be identified with a coding system. I am free to revoke my consent at any time and for any reason, without having to give an explanation and without having a negative impact on any present or future medical treatment.

I give my consent for my associated clinical data to be used as part of this research project. I agree to participate voluntarily.

I affirm to have been warned about the possibility of receiving information related to my health derived from heart pulses, electrocardiograms and blood samples.

I request information: YES/ NO

DATA: PATIENT SIGNATURE:

I note that I have explained the characteristics of the research project and the conservation conditions, if applicable, that will be applied to the conserved data.

Name of the Investigator or the person designated to provide the information:.....

DATA: INVESTIGATOR SIGNATURE:

Annex IV - Questionnaire for a survey to assess the degree of awareness on ethics principles

During the execution of the project, a survey will be organised to assess the degree of knowledge of the project partners on the issues connected to ethics management. Below we present the questions that will be used for the survey.

ETHICS MANAGEMENT SURVEY

Organisational questions.

1. Is there an ethical manager in your organisation?
2. Who is responsible for taking decisions in case any ethics issue emerges? (please indicate the organisational body, such as the general director, the legal representative, etc.)
3. Is there an Ethical committee in your organisation? (YES, NO)
4. In case the Ethical committee is present, how many mabemmembers er are present? (indicate the number of members)
5. In case the Ethical committee is present, what is the composition? (all members are internal to the organisation, all members are external, members are partially internal and partially external)
6. Is there an ethical code of conduct in your organisation? (YES, NO)
7. Is there an organisational procedure for addressing ethics issues? (YES, NO)
8. Did the organisation perform the Horizon2020 ethical self-assessment?[9] (YES, NO)

Contracts and personnel

2. If present, is the ethical code of conduct part of the job contract with employees (full time and part time)? (YES, NO)
3. If present, is the necessity to adhere to the ethical code of conduct foreseen in the selection of professionals and suppliers? (YES, NO)

Training

1. Is ethics management part of the training of the scientific personnel? (YES, NO)
2. Is ethics management part of the training of the administrative and non scientific personnel? (YES, NO)
3. Is there a repository of ethics resources, such as reference documents, training material, MOOCs, that is accessible to personel? (YES, NO)

[9] The Horizon2020 form will be attached to the questionnaire.

Annex V - Ethics questionnaire for deliverables' reviewers

The quality management process for the preparation of project deliverables foresees a peer review approach. A checklist of questions will be provided to the reviewers to allow them to highlight ethics issues. Below we present the questions of the checklist.

CHECKLIST FOR DELIVERABLES' REVIEWERS

1. Did the research activity that underpinned the preparation of the deliverable involve human participants?
   If so:
   1.1. Were they volunteers?
   1.2. Did they provide informed consent?
   1.3. Did they belong to vulnerable groups?

2. Did research activity foresee physical interventions on participants?
   If so:
   2.1 Were any invasive techniques adopted?

3. Did the researchers performing the activities assess harms?
4. Did the researchers performing the activities assess benefits?

5. Did research involve collection and processing of personal data?
   If so:
   5.1. Were personal data (e.g. health, sexual lifestyle, ethnicity, political opinion, religious or philosophical conviction) collected?
   5.2. Were data collected in an anonymous form?
   5.3. Were data processed in an anonymous form?
   5.4. Were data shared (e.g. through reports, publications, presentations) in an anonymous form?
   5.5. Is the dataset mentioned in the project Data Management Plan?

6. Did the research activity require an authorisation or ethics committee opinion?
   If so:
   6.1. Were the authorisation or the opinion collected?

Annex VI - Publicly available resources on ethics management

Several resources focused on ethics in research are available online. Below is a list of resources from the project coordinator MOOCS database and from some major online training platforms (EdEx, MIT, Coursera, Futurelearn).

Being a researcher (in Information Science and Technology)
https://www.pok.polimi.it/courses/course-v1:Polimi+BAR101+2021_M10/about
The course provides a broad view of how to become and progress as a researcher. It spans over a wide range of topics, from the historical development of scientific thought to research methodology, to the pragmatics of publication, research funding, evaluation, and promotion in a researcher's career. It also stresses the ethical aspects of research. Although the course speaks about scientific research in general, it especially focuses on the field on Information and Communication Science and Technology.

Ethics of Artificial Intelligence
https://www.pok.polimi.it/courses/course-v1:Polimi+AI102+2021_M7/about
This course deals on how to reflect on the ethical, social, and cultural issues of AI and how to apply ethical frameworks to problems created, aggravated, or transformed by AI.

Fostering women's participation to STEM through MOOCs
https://www.pok.polimi.it/courses/course-v1:Polimi+FWM101+2021_M10/about
This course aims to raise awareness about the importance of gender balance in the STEM field and illustrates a tool for the creation of gender-balanced MOOCs

Introduction to Research Ethics: Working with People
https://www.futurelearn.com/courses/research-ethics-an-introduction
The course addresses how to conduct ethical research when working with people.

Research Ethics Online Training
https://globalhealthtrainingcentre.tghn.org/elearning/research-ethics/
The course is provided by the Global Health Training Centre. Research Ethics Online Training is adapted from an e-Learning course and resource package designed and produced by the World Health Organization (WHO) for use by internal staff. Research is a vital ingredient for improved global health and scientifically sound and ethically appropriate research is especially important in resource-poor settings where the need for locally applicable research findings is so great. Therefore, the WHO has very kindly granted permission for the adaption of this resource in a format and platform that is accessible to all.

Multidisciplinary Research Methods for Engineers

https://www.edx.org/course/multidisciplinary-research-methods-for-engineers?index=product&queryID=806dc8807ba19bbc6060623e99340218&position=2

Engineering is no longer limited to working in a single domain; nowadays engineers increasingly work in multidisciplinary fields. After this course researchers will be able to carry out all stages of multidisciplinary research using appropriate research methods.

Data Ethics, AI and Responsible Innovation

https://www.edx.org/course/Data-Ethics-AI-and-Responsible-Innovation?index=product&queryID=c67090f8b5eeb2f2db34d3c5d480830f&position=4

Our future is here and it relies on data. Medical robots, smart homes and cities, predictive policing, artificial intelligences – all are fuelled by data and all promise new benefits to society. But will these innovations benefit everyone? Who stands to gain and who is put at risk? How can we ensure that data is part of a just and sustainable world?

Ethics for Engineers: Artificial Intelligence

https://ocw.mit.edu/courses/chemical-engineering/10-01-ethics-for-engineers-artificial-intelligence-spring-2020/

Artificial Intelligence (AI), and the algorithmic judgment at its core, is developing at breakneck speed. This version of the popular Ethics for Engineers course focuses on the ethics issues involved in the latest developments of computer science.

Module 1: Introduction to Ethics in Machine Learning

https://ocw.mit.edu/resources/res-ec-001-exploring-fairness-in-machine-learning-for-international-development-spring-2020/module-one-introduction/

The module provides an introduction to how machine learning is used in international development. Objectives comprise:

- Explain the motivation for addressing ML ethics in international development
- Describe how ML is used in international development
- Identify limitations of ML
- Introduce ML ethics research

Ethics issues are also addressed in the course.

Qualitative Research Methods (including ethics principles)

https://www.coursera.org/learn/qualitative-methods

In this course you will be introduced to the basic ideas behind qualitative research in social science. You will learn about data collection, description, analysis and interpretation in qualitative research. Qualitative research often involves an iterative process. We will focus on the ingredients required for this process: data collection and analysis.

You won't learn how to use qualitative methods by just watching videos, so we put much stress on collecting data through observation and interviewing and on analysing and interpreting the collected data in other assignments.

Obviously, the most important concepts in qualitative research will be discussed, just as we will discuss quality criteria, good practices, ethics, writing some methods of analysis, and mixing methods.

Being a researcher

https://www.coursera.org/learn/being-researcher

The course provides a broad view of how to become and progress as a researcher. It spans over a wide range of topics, from the historical development of scientific thought to research methodology, to the pragmatics of publication, research funding, evaluation, and promotion in a researcher's career. It also stresses the ethical aspects of research. Although the course speaks about scientific research in general, it especially focuses on the field of Information and Communication Science and Technology.

The course is mainly directed to students engaging in research and beginning researchers. It may also be of interest for senior researchers in their role as supervisors or mentors, and to all those who are interested in how scientific research works. The main topics addressed in the course are:

- Research, its historical development, and its role in society
- Research methodology
- The products of research: publications and artifacts
- The professional researcher: roles and career progress
- Research evaluation, from peer review to bibliometrics
- Research ethics