IDEA4RC

Intelligent ecosystem to improve
the governance, the sharing, and the re-use
of health data for rare cancers

Deliverable 10.1

Ethics guidelines for enlargement addressing ethic issues arising in the wider community beyond IDEA4RC pilots cases

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Distribution List

Organization	Name of recipients
1 - Coord INT	A. Trama, P. Casali, L. Buratti, P. Baili, J. Fleming, L. Licitra, E. Martinelli,
2 - UDEU	A. Almeida, , U. Zulaika Zurimendi, N.. Kalocsay
3 - MME	F. Mercalli, M. Vitali
4 – UPM	E. Gaeta, G. Fico, L. Lopez, I. Alonso, C. Vera, M.T. Arredondo, M.F.
	Cabrera
5 - HL7	G. Cangioli, C. Chronaki, R. Gazzarata
6 - ECCP	S. Ziegler, A. Quesada, S. Schiffner, V. Tsiompanidou
7 – ENG	D. Pavia, A. Sperlea, E. Mancuso, M. Melideo, F. Saccà, V. Falanga, M.
	Rosa
8 - CERTH	K. Votis, A. Triantafyllidis, N. Laloumis
9 - UU	S. van Hees, Wouter Boon, E. Moors, M. Kahn-Parker, C. Egher
10 - DICOR	C. Lombardo, G. Pesce, G Ciliberto, A. Tonon,
10° - ACC	L. Villanova, P. De Paoli, G. Piaggio, M. Pallocca. A. De Nicolo
(Affiliated)	A. Lavelli, S. Poggianella, O. Mayora, A.M. Dallaserra
11 - FBK	F. Martin, E. Bosma. G. Geleijnse, A. Van Gestel
12 – IKNL	A. Sans, M. Brahmi, A. Pons, J-Y Blay, H. Crochet, J. Olaz, J. Bollard, C.
13 – CLB	Chemin-Airiau, H. Crochet
	B. Baujat, E. Koffi
14 - APHP	J Martin-Broto, N. Hindi, M. Martin Ruiz, A. Montero Manso, C. Roldàn
15 – FJD	Mogìo, D. Da Silva, A. Herrero, B. Barrios
16 -VGR	Magnus Kjellberg, L. De Verier, A. Muth
17 - MSCI	I. Lugowska, D. Kielczewska, M.Rosinska, A KAwecki , A., P. Rutkowski
18 - MUH	R. Knopp, A. Sediva, K. Kopeckova, A. Nohejlova Medkova, M. Vorisek
19 – OUS	M. Sending, O. Zaikova
20 – MMCI	J. Halamkova, I. Mladenkova, l. Tomastik, V. Novacek, T. Kazda, I.
	Mladenkova, O. Sapožnikov
21 - CLN	R. Szmuc, J. Poleszczuk, R. Lugowski

22 - FPNS	M. Barbeito Gomez, P. Parente, L. Carrajo Garcia, P. Ramos Vieiro
23 - TNO	E. Lazovik, L. Zilverberg, S. Dalmolen
24 - INF	ML Clementi, C. Sabelli
25 – UKE	S. Bauer, S. Lang, S. Mattheis, N. Midtank
26 - NIPH	S. Larønningen, J. Nygård

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Addressees of this document

This document is addressed to the whole IDEA4RC Consortium. It is an official deliverable for the project and shall be delivered at the European Commission and appointed experts.

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Abbreviations and definitions

Abbreviation	Definition
AI	Artificial Intelligence
APEC	Asia-Pacific Economic Cooperation
ASEAN	Association of Southeast Asian Nations
CoEs	Centres of Excellence involved in the IDEA4RC project
DPIA	Data Protection Impact Assessment
DPO	Data Protection Officer
ECHR	European Convention on Human Rights
EEAS	European External Action Service
EHDS	European Health Data Space
EU	European Union
FAIR	The FAIR principles standing for Findable, Accessible, Interoperable and Reusable
GDPR	General Data Protection Regulation
HLCM	High-Level Committee on Management of the UN
IDEA4RC	The European-funded project "Intelligent Ecosystem to improve the governance, the sharing, and the re-use of health Data for Rare Cancers"
IEEE	Institute of Electrical and Electronics Engineers
IRPC	Internet Rights and Principles Coalition
ISO	International Organisation for Standardisation
NGO	Non-Governmental Organisation

OECD	The Organisation for Economic Co-operation and Development
OECI	Organisation of European Cancer Institutes
UDHR	Universal Declaration of Human Rights
UN	United Nations
UNESCO	United Nations Educational, Scientific and Cultural Organization
WHO	World Health Organisation
WP	Work Package

EXECUTIVE SUMMARY

IDEA4RC seeks to establish the framework for the first European Data Ecosystem for Rare Cancers, combining data from various sources in multiple EU countries. By leveraging data on rare cancers held by hospitals, clinics and EURACAN, the project aims to combine data with emerging interoperability technologies and AI approaches for distributed data integration, federated analysis, and knowledge extraction from existing structured and unstructured health data. This can improve the delivery of care, facilitate patients' information and advance clinical and epidemiological research in rare cancers.

As such, the vision behind the IDEA4RC Ecosystem is to expand well beyond its initial partner hospitals and clinics, encompassing more and more data sources so as to optimise rare cancer research, and, consequently, improve treatment options.

Taking the above into consideration, the present deliverable focuses on one primary aspect of the IDEA4RC project: ethical requirements for enlargement, drawing and building upon the results of Deliverable 2.3 "Ethical data governance and reuse incentivization approach". Based on this, the present deliverable considers the results of the evolution of ethical and normative issues arising within IDEA4RC in order to best design post-project activities.

This deliverable accordingly addresses ethical issues arising in the wider community beyond IDEA4RC pilot cases. In order to identify the scope of enlargement, the present deliverable identifies the preliminary legal and contractual requirements for enlargement, with regulatory requirements for both European partners and extra-European partners. In identifying the core ethical requirements present worldwide, the deliverable presents and analyses relevant legislation and requirements at both an international and a European level.

Finally, building upon the ethics guidelines contained in D2.3, the deliverable presents the ethical considerations for enlargement. In order to achieve this, it introduces the Ethics by Design and By Default criteria that have been designed on the basis of the core ethical requirements on a global scale to assist in the identification and mitigation of ethical issues arising in research.

1. INTRODUCTION

1.1 Ethics

Ethics originally emerged as a field of philosophy during the antiquity, trying to establish a set of rules and principles guiding human behaviour.[1] The discussion surrounding ethics has been particularly prevalent in the field of medicine and healthcare, with the introduction of ethical principles dating back to the establishment of the Hippocratic oath.[2] Nonetheless, it wasn't until the 1960s that the field of Ethics involved in other disciplines, such as engineering, business and computer science, started being established as subjects of specialised studies.[3]

That being said, ethics is defined by a high degree of subjectivity,[4] varying contextually over time and space. As such, ethical principles present differences across fields and cultures, with elements considered ethical for certain groups not necessarily being deemed ethical to others. Different perspectives, visions, and understandings exist, with no universally accepted text of ethical requirements. As a result, the issue of addressing ethics persists, given its **context-driven character, and the need to minimise all subjectivity in the process**.

Alongside its position as a prominent branch of philosophy, ethics has also been integrated as a core component of legal and regulatory compliance. Since the 1960s, there has been a **systematic effort to "codify" ethics and transpose them into standards, normative sources and legislation**,[5] to establish a common ground of action for globalised societies. Within the European Union ('EU') context, particularly, ethical considerations have become of high relevance in the context of compliance with the overarching European legal framework, being encompassed in various pieces of legislation (e.g. the General Data Protection Regulation).[6]

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[1] Muel Kaptein and Johan Wempe, 'Three General Theories of Ethics and the Integrative Role of Integrity Theory' (2011) available at <https://ssrn.com/abstract=1940393> accessed 11 February 2025.

[2] Goran Stojanović, 'The Ethical Legacy of Hippocrates' (2020) Scr Med 2020;51 (4), pages 275-283.

[3] Sven Ove Hansson, The Ethics of Technology: Methods and Approaches (New York: Rowman & Littlefield International, 2017), pages 3-4.

[4] Gillon R., "It's all too subjective": scepticism about the possibility or use of philosophical medical ethics. Br Med J (Clin Res Ed). 1985 May 25;290(6481):1574-5.

[5] Idem no 3.

[6] European Commission, 'Ethics and data protection' (05 July 2021) available at <https://ec.europa.eu/info/funding-tenders/opportunities/docs/2021-2027/horizon/guidance/ethics-and-data-protection_he_en.pdf> accessed 11 February 2025.

It is worth noting that, in spite of said efforts, numerous ethical guidelines and standards have been put in place by different entities, in different fields and for different purposes. Particularly in research, **ethics has slowly turned into a core concept guiding research activities.**[7] acting as a mediator between achieving the research purposes, innovation, and abstinence from causing harm in any way, whether that involves humans, animals, the environment, or other interests. As put by the European Commission, "*ethics is concerned with the protection of individual rights like freedom and privacy, equality and fairness, avoiding harm and promoting individual well-being, and building a better and more sustainable society* ***often anticipating solutions that eventually becomes legal requirements to comply with***".[8]

1.2 Ethics within IDEA4RC

In the context of the IDEA4RC project, ethics refers to the **set of moral principles, values, and guidelines that govern the conduct of research and data utilisation related to rare cancers**. Given the project's objectives, IDEA4RC has acknowledged since the beginning the importance of ensuring the rights, privacy, and dignity of individuals whose data is involved.

Particularly in the context of the IDEA4RC project, managing data in an ethical manner that respects human rights and freedoms is a crucial point for the project's evolution and the achievement of its goals. Data ethics, in particular, can be described as the emerging branch of applied ethics, which studies and evaluates moral problems related to the generation, processing and sharing of data to implement morally sound conducts and values.[9]

Deliverable D2.3 had already examined and reviewed the ethical risks identified by relevant stakeholders, including patients and healthcare professionals, with the objective of identifying and encouraging the implementation of mitigation measures since the start. In this context, a set of

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[7] European Commission, 'Ethics Advisors and Ethics Advisory Boards Roles and Function in EU-Funded Projects' (15 February 2021) available at <https://ec.europa.eu/info/funding-tenders/opportunities/docs/2021-2027/horizon/guidance/roles-and-functions-of-ethics-advisory-ethics-advisory-boards-in-ec-funded-projects_he_en.pdf> accessed 15 January 2025.

[8] European Commission, 'Ethics By Design and Ethics of Use Approaches for Artificial Intelligence' (25 November 2021) <https://ec.europa.eu/info/funding-tenders/opportunities/docs/2021-2027/horizon/guidance/ethics-by-design-and-ethics-of-use-approaches-for-artificial-intelligence_he_en.pdf> accessed 19 December 2024.

[9] Luciano Floridi & Mariarosaria Taddeo, 'What Is Data Ethics?' [2016] 374 Phil. Transactions Royal Society A 1, 1.

Ethics by design and by default Guidelines was established, divided into the following phases for more efficient management:

1. **Preliminary phase**, containing the measures towards ethical compliance to be adopted before any data processing or sharing had commenced;
2. **Implementation phase,** providing for the ethical considerations once the IDEA4RC pilots had started their activities;
3. **Closing and Post-Implementation Phase**, aiming at the dual objective of ensuring that the outcomes can be further reused and, on the other, that the project's activities can continue beyond its lifecycle.

Such ethical considerations involved in the project's activities included, but were not limited to, personal data protection and security, minimising risks to participants, while maintaining transparency and accountability throughout and beyond the project's lifetime. The ethical treatment of personal data is essential for the respect of the individual and their fundamental rights, and this is one of the reasons why principles such as data protection, privacy, and confidentiality are so reoccurring in the ensuing guidelines for enlargement.

1.3 Ethics beyond IDEA4RC

Since its conception, the goal of IDEA4RC was to establish an Ecosystem that could be operational beyond the project's duration. As such, a multifaceted strategy has been adopted to ensure that the envisioned activities can be realised in a realistic and efficient manner. In order to best design its expansion strategy, a dedicated questionnaire was disseminated among partners, both on the research side, as well as their legal and management teams. In this regard, the key points with regards to governance beyond the project's lifecycle involving ethics included the following:

a) The **categories of actors able to reuse the IDEA4RC data**, to differentiate between commercial and non-commercial actors;

b) The **conditions for reusing the IDEA4RC data**, aiming at ensuring data privacy and security;

c) The **information required to be able to access the IDEA4RC platform**, taking into account the necessary documentation that would allow partners to better comply with legal requirements and ensure data privacy and security;

d) The **purposes** for which data can be reused, in order to ensure that it is used for legitimate purposes, related to rare cancer research or the improvement of treatment options;

e) The **publication** of all the information related to the possibility of reusing the IDEA4RC data, to ensure **transparency**.

In all of these aspects, ethics plays a central role given the sensitive nature of the data involved and the research objectives. As such, the present deliverable shall accordingly address ethical issues arising in the wider community beyond IDEA4RC pilot cases. In order to identify the scope of enlargement, the present deliverable identifies the preliminary legal and contractual requirements for enlargement, with regulatory requirements for both European and extra-European partners. In identifying the **core ethical requirements present worldwide**, the deliverable presents and analyses relevant legislation and requirements at both an international and a European level.

Finally, the present deliverable goes beyond health and data ethics, aiming to **expand the scope of the previously designed ethics guidelines**. Accordingly, in this context, ethics shall refer to the **set of moral principles, values, and guidelines that govern the conduct of research and data utilisation at a wider scope, encompassing an extended spectrum of research activities**.

2. METHODOLOGICAL APPROACH

This Deliverable identifies, analyses and presents the Ethics Guidelines for Enlargement, focusing on addressing ethical issues arising in the wider community beyond the IDEA4RC pilot cases. In order to better define the scope of said guidelines, the **preliminary legal and contractual requirements for enlargement** are identified, including the **regulatory requirements for both European and extra-European partners.**

What is more, the deliverable presents a review of the **core ethical requirements at a global level**, analysing relevant legislation and ethical requirements at both a European and an international level. In doing so, it extends the **regulatory analysis of ethical requirements** that are relevant not only to IDEA4RC activities, but to a **broader application**. The documentation was selected on the basis of the number of signatories parties and/or its importance in the respective fields.

A **comparative analysis** of all ethical requirements contained in each individual document is performed in order to identify a set of common recurring themes. Among those principles, a threshold was set to include only the principles appearing in at least half of the documents examined. As a result, a final set of principles for consideration to ensure compliance with Ethics by Design and by Default was established.

Leveraging on the above theoretical framework, and building on the Ethical Guidelines developed in the context of Deliverabe D2.3, a set of **Ethics by Design and by Default Guidelines in the form of criteria for enlargement** were developed to translate the core ethical requirements present worldwide into actionable and auditable requirements, in a manner that ensures that the criteria can be applied to all areas of research, while minimising subjectivity in the process.

3. PRELIMINARY LEGAL AND CONTRACTUAL REQUIREMENTS FOR ENLARGEMENT

As already established, the IDEA4RC project has placed ethical and regulatory compliance at the forefront of its activities, adopting and implementing a compliance-by-design and by-default approach. Previous deliverables have analysed in detail how compliance is tackled within the project both from an organisational perspective and at the infrastructure level.

The present section will delve deeper into the regulatory requirements that will be applicable beyond the project's lifecycle, ensuring that the IDEA4RC ecosystem remains operational. As such, it will focus on the regulatory requirements for both European and extra-European partners to be able to reuse the IDEA4RC data, in accordance with the applicable regulatory framework, which is heavily European-centric due to the partners' location.

Finally, this section will identify and present the contractual requirements of relevance for the expansion of the IDEA4RC Ecosystem. Up until this point, the contractual requirements in place among the IDEA4RC partners ensured the smooth operation of the project, while aiming at establishing a legal framework that would be flexible enough to facilitate its expansion. This section will describe precisely the requirements for the evolution of the contractual relationship between existing and future partners, as well as with external Data Users.

3.1 Regulatory Requirements for European partners

IDEA4RC aims to develop a federated ecosystem between the CoEs of the European Reference Network (ERN) on Rare Adult Solid Tumors (EURACAN) for the secondary use of data. The federated infrastructure ensures that any machine-learning algorithms are executed on multiple local datasets stored at isolated data sources, in this case the so-called IDEA4RC Capsules, are located at each respective Centre of Excellence location, in a decentralised collaborative learning setting. As such, no data used to produce the outputs ever leaves the local sites, while only aggregated data is shared with the Data User.

That being said, due to the nature of the data, purposes and ecosystem established, the two key Regulations that are applicable to the IDEA4RC enlargement are the General Data Protection Regulation ('GDPR') and the European Health Data Space ('EHDS') Regulation.

The GDPR establishes comprehensive requirements for the processing and sharing of personal data within the EU, including when performing research. As such, IDEA4RC partners must abide by a set of key requirements including:

1. **The identification of a Lawful Basis for Processing (Articles 6 and 9):** Data processing must be based on a lawful ground, such as compliance with a legal obligation, consent, performance of a task carried out in the public interest or in the exercise of official authority etc. As analysed in detail in Deliverables D2.3 and D8.2, the lawful basis has been a central point of the IDEA4RC framework, originally separately defined by each partner. Nonetheless, once the EHDS is in force, the lawful basis shall be homogenously defined as the performance of research (Article 9 par. 2(j) GDPR) necessary to comply with a legal obligation (Article 6 (c) GDPR) set out by the EHDS Regulation.
2. **Data Minimisation (Article 5(1)(c)):** Only personal data that is necessary for the specific research purpose shall be included in the IDEA4RC ecosystem and processed.
3. **Purpose Limitation (Article 5(1)(b)):** Personal data shall be processed for specified, legitimate purposes and not further processed in a manner incompatible with those purposes.
4. **Accountability (Article 5(2)):** Partners remain responsible for and must be able to demonstrate compliance with the GDPR principles.
5. **Transparency and Information (Articles 13 and 14):** Data subjects shall be informed about the processing of their personal data, including the research purposes recognised by IDEA4RC.
6. **Data Subject Rights (Articles 15-22):** Partners shall be mindful of the patients' rights to data access, rectification, erasure, restriction of processing, data portability, and objection to processing, where those are feasible considering the IDEA4RC infrastructure and the EHDS Regulation.
7. **Data Protection Impact Assessment (DPIA) (Article 35):** Where required, a DPIA must be conducted to assess and mitigate risks for patients whose data is analysed.
8. **Security of Processing (Article 32):** Appropriate technical and organisational measures must be implemented to ensure a level of security appropriate to the risk.

9. **Written Contractual Agreements (Article 28, Chapter V):** Where multiple parties are involved, a written contract must be in place outlining, among others, the roles, activities and security measures in place.
10. **International Data Transfers (Chapter V):** Where Data Users are located outside the EU, additional conditions may be applicable, including an analysis of the third-country legislation and further contractual requirements.

Moreover, the EHDS Regulation aims to establish a Data Space that will enhance individuals' access to and control over their personal electronic health data within healthcare contexts. It also seeks to facilitate the use of electronic health data for societal benefits, including research, innovation, policymaking etc. Given IDEA4RC's establishment of such a data space, partners must ensure:

1. **Identification of legitimate purposes of secondary use of health data (Articles 53 and 54)**: Data can only be reused for lawful purposes, excluding, for instance, any reuse for marketing activities or to produce detrimental decisions for patients etc.
2. **Identification of a lawful basis (Article 58 (a))**: Data Users are granted access to the data in accordance with the legal bases of the GDPR.
3. **Implementation of technical and organisational measures (Article 58 (b))**: The security of the data must be ensured at all times.
4. **Arrangements to ensure patients' rights (Article 58 (c) (d))**: Patients retain their rights and need to be able to enforce them.
5. **Transparency (Articles 58 and 59)**: Partners must make public the conditions for performing analyses on the data, as well as the results or outcomes of the projects for which the electronic health data were used. Similarly, they must publish an activity report every two years.
6. **Data Permit (Article 60 par. 1)**: Partners must provide access to the IDEA4RC ecosystem only once the conditions are fulfilled and upon the issuance of a data permit.
7. **Timely response (Article 60 par. 2):** Partners must handle and respond to data access requests no later than three months from the receipt of the request.
8. **Auditing Data Users (Article 63)**: Partners must be able to monitor and supervise the use of the data, requesting and receiving all documentation to assess compliance.

9. **Compliance with Data Permit requirements (Article 61)**: When acting as a Data User, partners must comply with all the requirements included in the data permit.

In addition to the above, and subject to local procedures and requirements, partners may be required to acquire an Ethical Approval for the performance of the research activities.

The IDEA4RC Ecosystem has fully taken into account the divergences among the implementation of the regulations at a Member State level, particularly the GDPR, as was in detail described in Deliverable D2.3 "Ethical data governance and reuse incentivization approach" and Deliverable D8.2 "Pilot Data Governance". Elements such as the differences between the applicable legal bases have already been mapped and are expected to be homogenized with the introduction of the EHDS Regulation.

In addition to the previously discussed elements, there may be further divergences among Member States, including on the need to perform a Data Protection Impact Assessment, as well as the need to acquire an Ethical Approval, which may differ even at a regional level within one Member State.

The manner in which the IDEA4RC Ecosystem and platform have been designed takes precisely into account the need to provide a system as flexible as possible to accommodate the varying compliance obligations of partners. As such, the IDEA4RC Ecosystem does not aim at imposing a certain compliance model on partners, but provides them with the flexibility to integrate their compliance requirements into the infrastructure. New partners entering the ecosystem shall first be called to identify the regulatory and ethical requirements they need to abide by, as well as the documentation to that end, in order to fully integrate them into the IDEA4RC process.

All of the above requirements are already encompassed within the IDEA4RC infrastructure, as further detailed in deliverables D3.2 "Policy Manager API implementation" and D7.2 "Toolkit trust management".

3.2 Regulatory Requirement for extra-European partners

Partners located outside the territory of the Union must still abide by the above-described requirements in order to both become a part of the IDEA4RC Ecosystem and benefit from its data. As a result, extra-European partners must ensure that they can comply with the above-described requirements and that there are no circumstances that could endanger that.

As established, the IDEA4RC Ecosystem is designed in accordance with the GDPR and the EHDS Regulation requirements. As such, both European and extra-European must abide by the requirements of said regulatory framework, as enshrined in the IDEA4RC infrastructure.

In this context, they will need to provide an assessment of their applicable legislation and administrative practices demonstrating that they cannot endanger the IDEA4RC ecosystem, the confidentiality of its data and the privacy of patients.

Additionally, they shall prepare and provide the necessary documentation, including a Data Protection Impact Assessment, Ethical Approvals, a description of the security measures in place etc., as well as the demonstration of how they will ensure that patients' rights remain enforceable, where applicable.

Similarly, they shall become a party to the contractual arrangements, duly signing and committing to comply with the requirements described therein, as well as with applicable legislation. Said commitments shall be enforceable before European courts to ensure accountability.

3.3 Contractual Requirements

Considering the multitude of stakeholders involved in the IDEA4RC ecosystem, as well as its envisioned expansion, it is anticipated that each organisation has in place its own procedures and, by extension, contractual requirements, including regarding the following elements:

a. Pre-contractual procedures and documentation, including the need to perform a Data Protection Impact Assessment;
b. Form of contractual arrangements, whether bilateral or multilateral;
c. Ad hoc contractual clauses, including on duration, conditions and restrictions.

Hence, it becomes apparent that there is a need for increased flexibility in the contractual arrangements among the stakeholders. Following up on the work performed within previous research projects, including Gatekeeper[10], a unilateral contractual model has been developed and its official validation is being pursued. Using this model, the time and cost-consuming process of negotiating and signing a multitude of bilateral agreements or a multilateral agreement among

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[10] Gatekeeper Project, Grant agreement ID: 857223.

numerous partners is simplified, since each stakeholder can define its own conditions and commit to abide by the necessary legal requirements.

Given that the IDEA4RC Ecosystem is designed to be operational in accordance with the GDPR and the EHDS Regulation, the contractual requirements shall be in alignment with those of said regulations. As such, both European and extra-European partners shall need to abide by the same set of requirements if they wish to participate and/or benefit from the ecosystem. As the implementation of the EHDS Regulation progresses, with the integration of third countries and international organisations anticipated in 2034, the IDEA4RC Ecosystem shall be further aligned with evolving needs and requirements.

In either case, the contracts in place, in alignment with the GDPR and the EHDS Regulation, shall include the following information:

a. A description of the dataset upon which the analysis is to be performed;
b. The data analyses that are permitted;
c. The purposes for which the data analyses can be performed;
d. Any costs incurred;
e. The identification of each party's role;
f. The conditions for reuse, including, among others:
    i. The obligations of each party;
    ii. The need to communicate any crucial findings;
    iii. The technical and organisational measures required;
g. The prohibition of any attempt to re-identify the data subjects;
h. The duration of the data analyses permitted;
i. The conditions for publication of results;
j. The consequences in case of infringement;
k. The documentation provided beforehand, including, for instance, a study protocol or an Ethical Approval.

Where any parties, whether providing or receiving data, are located outside of the EU, further safeguards shall be in place, including an assessment of the third-country legislation, in order to ensure that the data remains protected and is used exclusively for legitimate purposes.

4. REGULATORY ANALYSIS OF ETHICAL REQUIREMENTS

Given the above-highlighted importance of ethical compliance, especially considering the sensitive nature of the IDEA4RC data and the importance of the research, the present section will provide an overview of the most prevalent ethical requirements at an international level.

In order to achieve this, a total of 52 normative documents have been analysed so as to identify the core ethical principles enshrined in relevant normative documents worldwide. Some of these documents were examined at a preliminary level within the scope of the IDEA4RC pilot cases, as reported also in Deliverable D2.3.

Nonetheless, to address ethical issues arising in the wider community, the scope is expanded in the present deliverable beyond those with relevance to ethics in healthcare. The complete analysis of the framework is included in Annex I and addresses the ethical requirements beyond data utilisation related only to rare cancers, focusing on the identification of ethical principles, values, and guidelines, that served as the baseline for the translation into criteria to assess ethical compliance.

4.1 Ethics in a Multijurisdictional Framework

As anticipated, the analysis of the ethical requirements gives rise to crucial elements surrounding ethics, namely the lack of a unanimously accepted instrument at a global level. As will be further analysed below, certain measures were implemented to ensure the highest degree of acceptability among countries, regardless of the differences in the legislative pieces to which they are subject, whether national, regional or international, while maintaining a high degree of protection.

Taking the above inherent element of ethics into consideration, the principles identified and the guidelines proposed in the form of criteria have been designed precisely to establish a common ground that ensures research abides by as widely acceptable ethics requirements as possible. While the differences in the regulatory frameworks among the various jurisdictions are an important factor, the guidelines and criteria proposed aim at minimizing such subjective elements.

In line with previous work in the field,[11] the rationale behind the effort to propose ethical standards focuses precisely on widely accepted principles, as will be further discussed below. The wording of

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[11] Winkler, E.A. Are universal ethics necessary? And possible? A systematic theory of universal ethics and a code for global moral education. SN Soc Sci 2, 66 (2022).

the standards proposed focuses on the elimination of subjectivity, while also ensuring that the means of demonstrating compliance with the requirements of the criteria leaves room for cultural diversity.

4.2 Bridging the Gap between Established Research Ethics Frameworks and Emerging Regulations

The analysis included in Annex delves deeper into the most prevalent ethical requirements at an international level, spanning a total of 52 normative documents. Some are well-established frameworks, deeply rooted in the realm of ethics (such as the Universal Declaration of Human Rights which dates back to 1948), while others have been adopted as recently as this year (e.g. the EHDS Regulation which was published in the Official Journal of the European Union in March 2025). The interaction of such frameworks could potentially lead to either conflicts among the requirements or gaps.

This interaction has already been considered for the establishment of the criteria and ethical guidelines, in order to promote certainty when applying the criteria, as well as when reviewing and auditing compliance with them. As demonstrated in the analysis, the ethical principles enshrined in both existing and emerging regulatory frameworks in reality do not raise any conflicts, as the emerging regulations are fully aligned with previously recognised principles.

In fact, emerging regulations either provide a more detailed methodology for applying ethical principles in specific contexts (such as the use of AI in research), or adapt the ethical principles to the evolving technological and regulatory framework. An example of the latter constitutes the EHDS Regulation, which adapts ethical principles, such as privacy and the no-harm principle, to the upcoming framework for data sharing for research.

As a result, the criteria and guidelines detailed below are reflecting precisely this evolution in the regulatory frameworks, so as to stay up-to-date with regulatory as well as technological needs. Thus, existing ethical frameworks within the context of IDEA4RC are fully integrated into updated requirements to comply with emerging regulations.

5. IDENTIFIED ETHICAL ISSUES RELATED TO ENLARGEMENT

Taking the above into consideration, it becomes evident that ethical considerations play a key part in the expansion of the IDEA4RC Ecosystem. As already depicted in Deliverable D2.3, the main stakeholders identified in the context of the IDEA4RC project include:

- Patients
- Patients' family
- Patient organizations
- Physicians/doctors
- Hospitals
- EURACAN CoEs
- European Reference Networks
- DIGICORE network
- OECI and other medical societies
- Data Protection Authorities
- Hospital DPOs
- Health authorities
- Public authorities
- Pharmaceutical companies
- Health IT businesses
- Research centres
- NGOs (for later stages)
- Private foundations funding research in the field of rare cancers

The above list, as further visualised below, remains relevant when discussing enlargement.

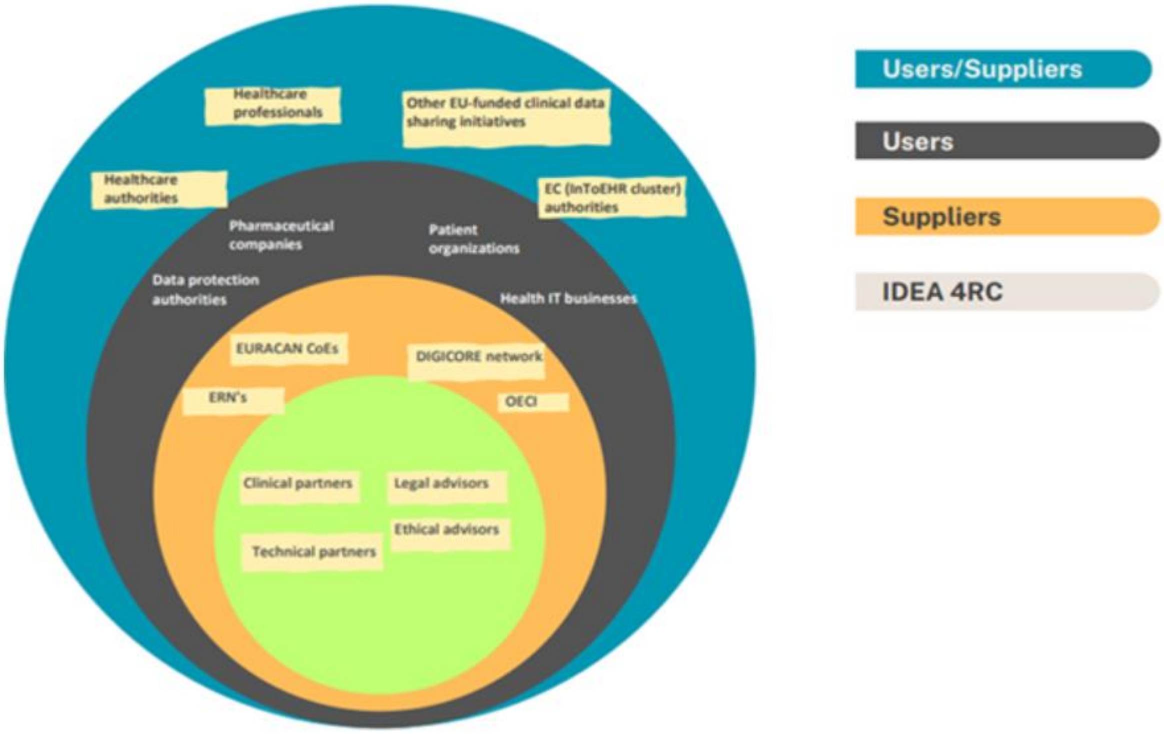

Figure 1 – Visualisation of the main stakeholders identified in the context of the IDEA4RC project

All of the above-described categories may be located within the EU, but the potential of involving non-EU stakeholders, whether as suppliers or users of the IDEA4RC ecosystem, cannot be excluded. This raises an important question of ensuring that the **third-country legislation and ethical norms are compatible with those reflected in the IDEA4RC ecosystem**.

In this regard, it is crucial to ensure that all partners entering the ecosystem abide by the requirements established within the IDEA4RC, whether ethical or regulatory. This, by default, contains EU frameworks, including the GDPR, the EHDS Regulation and the AI Act, taking into account that the IDEA4RC Ecosystem has been designed by default to be aligned with them.

As such, partners interested to join the IDEA4RC Ecosystem shall need to assess and demonstrate that the normative framework to which they are subject does not endanger the IDEA4RC Ecosystem, and does not impede compliance.

In addition to the above, and considering the expanding ecosystem of data, the need to remain **transparent** remains, in particular as to:

a. **which data** is included in the IDEA4RC ecosystem;

b. for **which purposes** the data can be reused;

c. **who** can reuse the data;

d. under which **conditions** the data can be reused;

e. how **patients' rights** remain enforceable;

f. the **technical and organisational measures** in place to ensure patients' data privacy and security.

As previously mentioned, these elements have been a key point of discussion within the project, aiming at a **dual objective**:

i. **Ensuring that patients remain empowered**, fully comprehending how their data is used to promote research in the field of rare cancers;

ii. **Ensuring that Data Users can clearly understand the conditions** under which they can reuse the data **and comply** with all relevant requirements.

Equally essential remains the need to ensure the **data quality** in a growing ecosystem of supplying partners. In this regard, **a clear set of rules and guidelines** to homogenise the data format, as well as **adherence to established standards** have been a crucial element of consideration since the start of the project.

Of course, the IDEA4RC policies and guidelines are meant to be living documents, evolving along with the project. Said policies and procedures shall take into account, among others, the need to comply with the identified ethical framework, as well as to mitigate any conflicts of interests or disputes among partners regarding the governance of the IDEA4RC Ecosystem. As further required within the ethics criteria themselves, all such processes and policies established are meant to be **reviewed on a regular basis to reflect the developments within the project and within regulations**.

Through the contact form provided in the platform, external parties, including Data Users and data subjects, can request further information on such procedures, as well as to raise issues. Where **ethical issues** are identified within IDEA4RC or raised by external parties, the policies and procedures established shall require a review of the issue, an assessment of its impact, whether past, present or future, as well as the **mitigation measures**.

Finally, the issue of **complying with administrative procedures in largely unhomogenised fields** remains a crucial point of consideration for enlargement. With the introduction of non-IDEA4RC partners whether as suppliers or users, the procedures and documentation required may vary, especially in the field of contractual agreements, Data Protection Impact Assessments, and Ethical Approvals. This is the main reason behind ensuring that the infrastructure remains as flexible as possible to ensure that all such needs can be accommodated.

As further detailed in Deliverable D7.2 "Toolkit trust management", the infrastructure has been designed to be **as flexible as possible** so as to integrate evolving ethical and regulatory requirements of the IDEA4RC Ecosystem as a whole, but also each individual partner participating in it. Based on the procedures required in each Centre of Excellence, **the partners can define the roles participating in the review, rejection or acceptance of data access requests and applications**, including but not limited to scientific coordinators, legal experts, data protection officers and ethics committees.

6. METHODOLOGY FOR CRITERIA GENERATION

The present section will provide further insight on the methodology deployed for the development of the Ethics By Design Criteria for assessment. It will explain the rationale and purpose, as well as the overview of the principles identified, including the explanation of which principles were then used as the baseline for the criteria themselves.

6.1 Purpose and Rationale of Criteria Generation

As previously mentioned, Deliverable D2.3 already included a set of initial guidelines for enlargement. The question remained, however, of how these guidelines, as well as the additional requirements identified throughout the project could be turned into an easy-to-use methodology for assessing compliance with Ethics. In this context, it was deemed more effective and user-friendly to turn the guidelines into auditable criteria that can be used not only within IDEA4RC but also beyond to assess the compliance with ethical dispositions.

As such, the Ethics by Design and By Default Criteria were designed to enable researchers to review and assess the alignment of their research activities with broadly-recognised ethical requirements. In this regard, the criteria can be applied by any stakeholder performing research, including academics, research organisations, as well as commercial actors and the industry when performing research.

Taking into account the previously analysed subjective character of Ethics, the criteria were developed with a view to minimise this subjective element as much as possible, ensuring that the ethical requirements therein described would be applicable regardless of location or context.

6.2 Methodological approach

In order to consolidate the core ethical requirements to be translated into criteria, the first necessary step was to identify the main ethical requirements, as presented above. This examination started with the most relevant, authoritative sources of international laws, before moving to the ambit of EU law. Several international standards were further examined, as well as any other requirements and guidelines relevant to the field of ethics.

Following the initial mapping of normative documents, a comparative analysis was performed including the primary ethical requirements contained in each individual document. As a result of this comparative analysis, the identification of common, recurring themes became possible.

For the purposes of this analysis, all normative documents utilised were given the same weight and a threshold of 50% was set. Accordingly, the recurring principles included in the criteria were determined based on whether they were included in at least 50% of the documents examined.

Finally, the baseline principles were grouped into larger thematic categories to facilitate the review of compliance. The criteria were created in a manner that is understood by non-legal experts as well, while ensuring researchers are adequately guided on the means to ensure and demonstrate compliance.

6.3 Scope of examination

As outlined in the present deliverable, providing the Regulatory Analysis of Ethical Requirements, a total of 52 normative documents were analysed in the process of identifying the core ethical requirements at a global level. These documents cover a wide range of activities, contexts and locations so as to ensure as much as possible the objective character of the criteria developed. For reference, the list of consulted normative documents is accordingly as follows:

6.3.1 Under International Law

1) Universal Declaration of Human Rights
2) Declaration of Helsinki
3) Universal Declaration on Bioethics and Human Rights
4) European Convention on Human Rights
5) OECD Good Practice Principles for Data Ethics in the Public Sector
6) International Ethical Guidelines for Health-related Research Involving Humans
7) WMA Declaration of Taipei on Ethical Considerations regarding Health Databases and Biobanks
8) Convention for the Protection of Individuals with regard to Automatic Processing of Personal Data

9) UN Personal Data Protection and Privacy Principles
10) International Covenant on Economic, Social and Cultural Rights
11) International Covenant on Civil and Political Rights
12) Convention on the Rights of the Child
13) Convention on the Elimination of All Forms of Discrimination against Women
14) International Convention on the Elimination of All Forms of Racial Discrimination
15) International Convention on the Protection of All Migrant Workers and Members of Their Families
16) American Convention on Human Rights
17) Cairo Declaration on Human rights in Islam
18) Arab Charter on Human Rights
19) Declaration of Principles on Freedom of Expression and Access to Information in Africa
20) African Charter on the Rights and Welfare of the Child
21) Human Rights Declaration of the Association of Southeast Asian Nations
22) Asia-Pacific Economic Cooperation Privacy Framework

6.3.2 Under European Law

1) Charter of Fundamental Rights of the European Union
2) General Data Protection Regulation
3) European Health Data Space Regulation
4) Data Act
5) Digital Services Act
6) Artificial Intelligence Act
7) Data Governance Act
8) Cybersecurity Act

9) Digital Markets Act
10) Law Enforcement Directive

6.3.3 International Standards

1) ISO/IEC TR 24368:2022 Information technology — Artificial intelligence — Overview of ethical and societal concern
2) ISO 26000:2010 Guidance on social responsibility
3) ISO/IEC 27001:2022 Information security, cybersecurity and privacy protection – Information security management systems – Requirements
4) ISO/IEC 27701:2019 Security techniques — Extension to ISO/IEC 27001 and ISO/IEC 27002 for privacy information management — Requirements and guidelines
5) IEEE Standard Model Process for Addressing Ethical Concerns during System Design

6.3.4 Other Requirements / Guidelines

1) The European Code of Conduct for Research Integrity
2) Code of Ethics for Data-Based Value Creation
3) European Ethical Principles for Digital Health
4) FAIR Principles
5) EEAS Joint Declaration on privacy and the protection of personal data
6) Ethics by Design and Ethics of Use Approaches for Artificial Intelligence
7) European Commission Ethics Guidelines for Trustworthy AI
8) European Commission 2030 Digital Compass: The European Way for the Digital Decade
9) OECD Privacy Principles
10) OECD AI Principles
11) UNESCO Recommendation on the Ethics of Artificial Intelligence
12) IEEE General Principles of Ethically Aligned Design
13) Asilomar AI Principles

14) Paris Call for Trust and Security in Cyberspace Principles
15) IRPC Charter of Human Rights and Principles for the Internet

6.4 Ethics by Design and by Default Core Requirements

Using the methodological approach described above, 40 principles have arisen in total and were, thus, investigated as recurring themes within the analysed documents. Said principles are presented at the table below. Where the themes were considered too closely correlated, such as in the case of privacy and personal data protection, the principles were merged into one, considering the similarities in the requirements entailed.

Principle	Principle
Transparency	Consent
Privacy / Data protection	Right to effective remedy / redress / rectification
Respect for Human life / rights	Purpose limitation
Accountability	Human Review / Monitoring / Intervention in the use of AI
Security	Control
Human Safety	Right to Health
Fairness	Lawfulness
Accessible	Intellectual property rights Protection
Confidentiality	Proportionality
Risk management and mitigation	Inclusiveness
Non-discrimination	Diversity
Integrity	Freedom of expression
Human rights / Fundamental rights	Freedom of thought, conscience and religion
Environment / Sustainability	Care
Accuracy	Data / Research Outcomes Findability

Human autonomy / Moral agency	Interoperability
Human dignity	Reusability of results
Right to erasure / to be forgotten / deletion	Protection of children
Openness	Gender Equality
Trust	Peace

Table 1 – Ethical principles identified as reoccurring themes in consulted normative documents for Ethics by Design and by Default

Based on this analysis, 22 ethical principles surpassed the 50% threshold, and were, accordingly, considered as the **core requirements for Ethics by Design and by Default**:

Principle	%
1. Privacy / Data protection	88,46
2. Security	88,46
3. Respect	84,62
4. Safety	82,69
5. Non-discrimination	82,69
6. Human rights / Fundamental rights	78,85
7. Accessible	78,85
8. Fairness	75,00
9. Health	73,08
10. Consent	67,31
11. Human Review / Monitoring / Intervention in the use of AI	67,31
12. Right to effective remedy / redress / rectification	63,46

13. Transparency	61,54
14. Accountability	59,62
15. Protection of children	59,62
16. Confidentiality	59,62
17. Human dignity	59,62
18. Risk management and mitigation	57,69
19. Integrity	57,69
20. Lawfulness	55,77
21. Environment / Sustainability	53,85
22. Women / gender equality	51,92

Table 2 – Ethical principles surpassing the 50% threshold of appearance in consulted normative documents for Ethics by Design and by Default

7. ETHICS CRITERIA FOR ENLARGEMENT

As a result of the above-described analysis, a set of criteria was generated. Therefore, the aforementioned core Ethics by Design and by Default requirements were structured around 14 dimensions, clustered into 3 main categories, as follows:

A. **Transparency and Accountability**
   1. Transparency and Access to Information
   2. Accountability, Right to Effective Remedy and Redress
   3. Human Oversight
   4. Integrity

B. **Rule of Law and Equality of Treatment**
   5. Lawfulness Compliance
   6. Equality of Treatment and Non-Discrimination
   7. Women and Gender Equality
   8. Ensuring Human Rights and Fundamental Rights
   9. Fairness, Respect, and Consent

C. **Duty to Care and Protect**
   10. Risk Mitigation, Precautionary Principle, Security, and Safety
   11. Protection of Children
   12. Preserving Privacy, Data Protection, and Confidentiality
   13. Protecting Health
   14. Protecting the Environment and Sustainability

For each of these dimensions, a clear definition was provided in order to ensure the homogenous understanding and application of the criteria, which is found alongside the criteria. This was deemed necessary, as most of the normative documents examined present certain variations in the definitions or different definitions altogether, frequently focusing on different aspects of the principle.

Each of these dimensions was further analysed into additional criteria to ensure that the ensuing requirements were adequately addressed. Each criterion is marked by a unique reference identifier to enhance usability and traceability. What is more, each criterion clearly indicates the conditions under which it is applicable, as well as the stakeholders to which it applies.

Similarly, the criteria are accompanied by further guidance explaining the applicable requirements, as well as providing good practices and recommendations. Finally, a list of suggested means of verification accompanies the criteria in order to facilitate compliance and auditability in a manner that enhances reproducibility and objectivity.

It is worth highlighting that the suggested means of verification provide guidance to partners on how compliance with the Ethics by Design and by Default criteria can be demonstrated. As mentioned above, such means of verification leave room for jurisdictional and cultural diversity, while ensuring auditability. As such, they focus on written documentation, such as ethical impact assessments, so as to ensure compliance across the board with the existence of available, accessible, affordable rectification avenues that are capable of providing appropriate redress.

At the same time, the criteria, along with the guidance and means of verification have been designed to be auditable by external auditors who review and validate compliance with the requirements enshrined. Where the criteria requirements are not met, the research activity cannot be deemed compliant with the Ethics by Design and By Default criteria and redress mechanisms shall be made available.

Leveraging on the methodology developed by the European Centre for Certification and Privacy ('ECCP') in the context of Europrivacy, the first European Data Protection Seal approved by the European Data Board ('EDPB'), the criteria have been submitted to the Europrivacy International Board of Experts for review, validation, and further exploitation. Once validated, they will be made available for use by research stakeholders, subject to intellectual property rights restrictions.

8. CONCLUSION

As already explained, ethics remains a field of high subjectivity, varying contextually over time and space. The present deliverable set out to address said culturally-driven normative field, while trying to minimise all subjectivity in the process of establishing appropriate ethics guidelines for the enlargement of the IDEA4RC activities.

Based on an extensive analysis, a better understanding of applicable legislation and normative requirements regarding ethical compliance has been achieved, not only in relation to IDEA4RC pilot cases, but also in the wider research community. Those requirements cover a wide range of instruments from international treaties and declarations to EU legislation to codes of ethics and standards.

Similarly, the requirements from a legal and contractual perspective with regards to enlargement have been compiled, so as to ensure that compliance can be achieved both within and beyond the European territory.

In order to facilitate the review of said ethical considerations that are found in diverse normative documents, the present Deliverable has also consolidated and defined the core Ethics by Design and by Default principles, which were then grouped into the 3 main categories of:

(1) transparency and accountability requirements,

(2) rule of law and equality of treatment requirements, and

(3) requirements of care and protection.

In order to promote compliance and reproducibility, the formalisation of the corresponding guidelines into actionable and auditable criteria was promoted. Said criteria developed serve as a baseline for the design, development and implementation of all research activities with regards to ethics, going far beyond the scope of solely IDEA4RC pilot cases. The further exploitation of the criteria is currently being pursued within ECCP.

ANNEX I

The present Annex includes the complete analysis of the legal framework performed in the context of developing the ethics guidelines and corresponding criteria.

Under International Law

The present sub-sections analyses the requirements at an international level, taking into account numerous ethical documents, whether broadly applicable or focusing on more specific topics and/or regions with great influence.

Universal Declaration of Human Rights

Starting with the 1948 Universal Declaration of Human Rights ('UDHR'), this was established as a common standard of human rights for all people and nations.[12] The UDHR recognises the following rights, that have an ethical dimension:

Universal Declaration of Human Rights Ethical Principles	
1)	Human freedom, equality and dignity;
2)	Non-discrimination;
3)	Privacy and confidentiality of personal information;
4)	A standard of living adequate for health and well-being, including, among others, medical care;
5)	Respect for human rights;
6)	Life, liberty and the security of persons;
7)	Fair and public hearing;
8)	Equal access to public service;
9)	Freely given and full consent;
10)	Right to an effective remedy;

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[12] Universal Declaration of Human Rights (adopted by General Assembly resolution 217A on 10 December 1948) <https://www.un.org/sites/un2.un.org/files/2021/03/udhr.pdf> accessed 13 December 2024.

11)	Freedom of opinion and expression;
12)	Freedom of thought, conscience and religion;
13)	Medical care;
14)	Protection of children;
15)	Equality of rights for men and women.

Table 3 Rights with an Ethical dimension in the Universal Declaration of Human Rights.

Declaration of Helsinki

The 1964 Declaration is listed in deliverable 2.3, outlining ethical principles for medical research involving human participants.[13] The ethical principles enumerated in the Declaration are as follows:

Declaration of Helsinki Ethical Principles	
1)	Prioritisation of the protection and respect of the participants involved;
2)	Protection of the life, health, dignity, integrity, right to self-determination, autonomy, privacy, and confidentiality of personal information of research subjects;
3)	Consideration of the ethical, legal and regulatory norms and standards for research involving human subjects;
4)	Conducting research in a manner that minimises possible environmental harm;
5)	Performing a risk assessment ensuring that the importance of the objective and the benefits outweigh any risks and burdens to the research subject;
6)	Abiding by generally accepted scientific principles;
7)	Justifying research through considering ethical matters and addressing the relevant requirements;

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[13] World Medical Association Declaration of Helsinki – Ethical Principles for Medical Research Involving Human Participants (last amended by the 75th WMA General Assembly, Helsinki, Finland, October 2024) <https://www.wma.net/policies-post/wma-declaration-of-helsinki/> accessed 13 December 2024.

8)	Informed, voluntary, freely given and written consent;
9)	Making research findings publicly available, focusing on a complete and accurate report;
10)	Transparency;
11)	Medical care;
12)	Accountability;
13)	Safety of participants;
14)	Fairness of inclusion in research;
15)	Research monitoring obligations;
16)	Striving for economic sustainability;
17)	Protection of intellectual property rights;
18)	Diversity.

Table 4 Declaration of Helsinki Ethical Principles.

Universal Declaration on Bioethics and Human Rights

The Universal Declaration on Bioethics and Human Rights,[14] adopted in 2005, is listed in deliverable 2.3, extending upon the rights recognised by the above-described Universal Declaration of Human Rights to address ethical issues related to medicine, life sciences and associated technologies as applied to human beings, taking into account their social, legal and environmental dimensions. The Declaration focuses on establishing the following key principles to be respected:

Universal Declaration on Bioethics on Human Rights Ethical Principles	
1)	Human dignity and human rights;
2)	Maximisation of benefit and minimisation of harm;
3)	Autonomy and individual responsibility;

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[14] Universal Declaration on Bioethics and Human Rights (adopted by UNESCO on 19 October 2005) <https://www.unesco.org/en/legal-affairs/universal-declaration-bioethics-and-human-rights?hub=66535> accessed 13 December 2024.

4)	Prior, free and informed consent, preferably in writing;
5)	Respect for human vulnerability and personal integrity;
6)	Privacy and confidentiality;
7)	Equality, justice and equity;
8)	Non-discrimination and non-stigmatisation;
9)	Respect for cultural diversity and pluralism;
10)	Solidarity and cooperation;
11)	Social responsibility and health;
12)	Sharing of benefits;
13)	Protecting future generations;
14)	Protection of the environment, the biosphere and biodiversity;
15)	Professionalism, honesty, integrity and transparency in decision-making;
16)	Establishment of societal dialogue and pluralistic public debates;
17)	Risk assessment and management;
18)	Safety;
19)	Accessibility of resources;
20)	Use or disclosure of information only for purposes for which it was collected or consented to;
21)	Periodic review of bioethical issues;
22)	Cultural diversity and pluralism;
23)	Protection of the health of women and children.

Table 5 Universal Declaration on Bioethics on Human Rights Ethical Principles.

European Convention on Human Rights

The European Convention on Human Rights, despite its name, is an international treaty aiming at protecting human rights and fundamental freedoms drafted by the Council of Europe and signed by all members of the Council, while several countries, including for instance the USA, have obtained an observer status.[15] The ECHR is listed in deliverable 2.3, with some of the most important principles for IDEA4RC enumerated therein. The Convention recognises the following principles:

European Convention on Human Rights Ethical Principles	
1)	Respect for human rights;
2)	Right to respect for private and family life;
3)	Freedom of thought, conscience and religion;
4)	Prohibition of discrimination;
5)	Right to liberty and security;
6)	Accessibility of public documents;
7)	Confidentiality;
8)	Protection of health;
9)	Right to an effective remedy;
10)	Protection against unlawfulness;
11)	Freedom of expression;
12)	Public safety;
13)	Interests of the child;
14)	Justice and peace.

Table 6 European Convention on Human Rights Ethical Principles.

OECD Good Practice Principles for Data Ethics in the Public Sector

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[15] Convention for the Protection of Human Rights and Fundamental Freedoms (European Convention on Human Rights, as amended) (Council of Europe, entered into force 1 June 2010) <https://www.echr.coe.int/documents/d/echr/Convention_ENG> accessed 13 December 2024.

The Organization for Economic Co-operation and Development ('OECD') has developed a set of principles for Data Ethics in the Public Sector.[16] Considering the nature of the activities performed within IDEA4RC and the character of most Centres of Excellence involved in the project as a form of public bodies, many general principles are outlined. The document outlines the following principles:

OECD Good Practice Principles for Data Ethics in the Public Sector	
1)	Managing data with integrity;
2)	Complying with relevant government-wide arrangements for trustworthy data access, sharing and use;
3)	Incorporating data ethical considerations into decision-making processes;
4)	Monitoring and controlling data inputs, and adopting a risk-based approach to the automation of decisions;
5)	Specifying the purpose of data use, especially for personal data;
6)	Establishing restrictions for data access, sharing and use;
7)	Ensuring practices are clear, inclusive and open;
8)	Ensuring data and any source code are openly available;
9)	Promoting individuals' and collectives' control over their data;
10)	Ensuring accountability and proactively managing risks;
11)	Transparency;
12)	Privacy;
13)	Security;
14)	Fairness of data use;
15)	Non-discrimination;

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[16] OECD Good Practice Principles for Data Ethics in the Public Sector (15 March 2021) <https://www.oecd.org/en/publications/oecd-good-practice-principles-for-data-ethics-in-the-public-sector_caa35b76-en.html> accessed 13 December 2024.

16)	Human rights and values;
17)	Awareness of potential environmental impact;
18)	Data accuracy;
19)	Human autonomy and dignity;
20)	Agency of individuals over their data;
21)	Choice for deletion of personal data records;
22)	Sustainability;
23)	Data protection;
24)	Obtaining data by lawful means;
25)	Proportionality;
26)	Diversity;
27)	Safety.

Table 7 OECD Good Practice Principles for Data Ethics in the Public Sector Ethical Principles.

International Ethical Guidelines for Health-related Research Involving Humans

The International Ethical Guidelines for Health-related Research Involving Humans is a set of guidelines aiming at establishing an ethical framework for health-related research which has been Prepared by the Council for International Organizations of Medical Sciences ('CIOMS') in collaboration with the World Health Organization ('WHO').[17] The Guidelines recognise the following core ethical principles:

International Ethical Guidelines for Health-related Research Involving Humans Ethical Principles	
1)	Ensuring social value of research, justifying risk to participants;

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[17] International Ethical Guidelines for Health-related Research Involving Humans (Fourth Edition, Geneva, Council for International Organizations of Medical Sciences (CIOMS), 2016) <https://www.who.int/docs/default-source/ethics/web-cioms-ethicalguidelines.pdf?sfvrsn=f62ee074_0> accessed 13 December 2024.

2)	Ensuring competency and integrity of research personnel;
3)	Respect and concern for the rights and welfare of individual participants;
4)	Fair distribution of benefits and burdens of research;
5)	Ensuring ethical and scientific review by competent and independent research ethics committees;
6)	Free and informed consent;
7)	Confidentiality and privacy;
8)	Protection of personal information;
9)	Accountability;
10)	Transparency;
11)	Safety;
12)	Security measures;
13)	Data accessibility;
14)	Upholding human rights;
15)	Accuracy of information and reports;
16)	Respect for individuals' autonomy;
17)	Openness of community consultation;
18)	Trust between communities and researchers;
19)	Contribution to a host country's sustainable capacity for health-related research and ethical review;
20)	Choice of control;
21)	Legality;
22)	Proportionality;
23)	Broad inclusion of different social groups in research;

24)	Obligation to care for participants' health needs;
25)	Inclusion of children and adolescents in research;
26)	Inclusion of women in research, gender balance.

Table 8 International Ethical Guidelines for Health-related Research Involving Humans Ethical Principles.

WMA Declaration of Taipei on Ethical Considerations regarding Health Databases and Biobanks

The Declaration on Ethical Considerations regarding Health Databases and Biobanks, as was revised in 2016, aims at establishing an adequate framework for the collection, storage and use of identifiable data and biological material beyond the individual care of patients, in concordance with the Declaration of Helsinki.[18] It provides for the following core ethical principles:

WMA Declaration of Taipei on Ethical Considerations regarding Health Databases and Biobanks Ethical Principles	
1)	Contribution to the benefit of society;
2)	Respect for dignity, autonomy, privacy and confidentiality;
3)	Informed consent;
4)	Access to information;
5)	Protection for ownership of materials, rights and privileges regarding intellectual property;
6)	Protection of individuals;
7)	Transparency;
8)	Participation and inclusion;
9)	Accountability;
10)	Security measures to prevent unauthorised access or inappropriate sharing;

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[18] World Medical Association Declaration of Taipei on Ethical Considerations regarding Health Databases and Biobanks (revised by the 67th WMA General Assembly, Taipei, Taiwan, October 2016) <https://www.wma.net/policies-post/wma-declaration-of-taipei-on-ethical-considerations-regarding-health-databases-and-biobanks/> accessed 13 December 2024.

11)	Prevention of discrimination;
12)	Maintaining trust and integrity;
13)	Review mechanisms;
14)	Right of individuals to exercise control over the use of their personal data;
15)	Protection of health;
16)	Data protection;
17)	Care of patients;
18)	Regard for safety;
19)	Respect for fundamental rights.

Table 9 WMA Declaration of Taipei on Ethical Considerations regarding Health Databases and Biobanks Ethical Principles.

Convention for the Protection of Individuals with regard to Automatic Processing of Personal Data

The 1981 Convention for the Protection of Individuals with regard to Automatic Processing of Personal Data is an instrument of the Council of Europe, entering into force in 1985.[19] It was the first legally binding international instrument in the data protection field, requiring parties to take the necessary steps in their domestic legislation to apply its principles, to ensure respect in their territory for the fundamental human rights of individuals regarding processing of personal data. The following core ethical principles encompassed are:

Convention for the Protection of Individuals with regard to Automatic Processing of Personal Data Ethical Principles	
1)	Fair and lawful obtaining and processing of personal data;
2)	Storage of personal data undergoing automatic processing for specified and legitimate purposes and not used in a way incompatible with those purposes;

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[19] Convention for the Protection of Individuals with regard to Automatic Processing of Personal Data (Council of Europe, entered into force 1 October 1985) <https://rm.coe.int/1680078b37> accessed 13 December 2024.

3)	Ensuring that personal data undergoing automatic processing is adequate, relevant and not excessive in relation to the purposes for which they are stored;
4)	Ensuring that personal data undergoing automatic processing is accurate and, where necessary, kept up to date;
5)	Preservation of personal data undergoing automatic processing in a form which permits identification of the data subjects for no longer than is required for the purpose for which those data are stored;
6)	Ensuring that personal data revealing racial origin, political origin, political opinions or religious or other beliefs, as well as concerning health or sexual life, or relating to criminal convictions, may not be processed automatically unless domestic law provides appropriate safeguards;
7)	Ensuring that appropriate security measures are taken for the protection of personal data stored in automated data files;
8)	Ensuring that data subjects are enabled to establish the existence of an automated personal data file, its main purposes, as well as the identity and habitual residence or principal place of business of the controller of the file;
9)	Ensuring that data subjects are enabled to obtain at reasonable intervals and without excessive delay or expense confirmation of whether personal data relating to him are stored in the automated data file as well as communication to him of such data in an intelligible form;
10)	Ensuring that data subjects are enabled to obtain rectification or erasure of data if these have been processed contrary to the applicable law;
11)	Ensuring that data subjects are enabled to have a remedy if a request for confirmation or rectification or erasure is not complied with;
12)	Right to privacy;
13)	Confidentiality;
14)	Respect for human rights;

15)	Data protection;
16)	Public safety.

Table 10 Convention for the Protection of Individuals with regard to Automatic Processing of Personal Data Ethical Principles.

UN Personal Data Protection and Privacy Principles

The Personal Data Protection and Privacy Principles were adopted by the High-Level Committee on Management (HLCM) of the United Nations at its 36th Meeting in 2018.[20] They outline the following main ethical principles:

UN Personal Data Protection and Privacy Principles	
1)	Fair and legitimate data processing;
2)	Purpose specification, considering the balancing of citizens' rights, freedoms and interests;
3)	Relevant, limited and adequate to what is considered as necessary processing of personal data;
4)	Retention of personal data only for the time that is necessary;
5)	Data accuracy and, where necessary, updates to fulfil the specified purposes;
6)	Processing personal data with due regard to confidentiality;
7)	Ensuring organisational, administrative, physical and technical safeguards and procedures are implemented to protect the security of personal data, including against or from unauthorized or accidental access, damage, loss or other risks presented by data processing;
8)	Ensuring processing of personal data is carried out with transparency to the data subjects, as appropriate and whenever possible;

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[20] UN Personal Data Protection and Privacy Principles (HLCM, adopted on 11 October 2018) <https://unsceb.org/principles-personal-data-protection-and-privacy-listing> accessed 13 December 2024.

9)	Transferring personal data to a third party only if satisfied that the third party affords appropriate protection for the personal data;
10)	Accountability: adequate policies and mechanisms should be in place to adhere to these principles;
11)	Privacy;
12)	Conducting risk-benefit assessments;
13)	Processing of personal data in a non-discriminatory, gender sensitive manner;
14)	Respect for human rights;
15)	Informing on how to request access, verification, rectification, and/or deletion of personal data;
16)	Consent of the data subject;
17)	Data protection;
18)	Caution when processing any data pertaining to vulnerable or marginalised individuals and groups of individuals, including children;
19)	Gender sensitivity.

Table 11 UN Personal Data Protection and Privacy Principles.

International Covenant on Economic, Social and Cultural Rights

The International Covenant on Economic, Social and Cultural Rights is a core international human rights instrument of the United Nations, adopted through a 1966 UN General Assembly resolution.[21] It encompasses the following primary ethical requirements:

International Covenant on Economic, Social and Cultural Rights Ethical Principles	
1)	Protection of national security and public order;
2)	Safe and healthy working conditions;

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[21] International Covenant on Economic, Social and Cultural Rights (adopted by General Assembly resolution 2200A (XXI) on 16 December 1966) <https://www.ohchr.org/sites/default/files/cescr.pdf> accessed 16 December 2024.

3)	Fair wages;
4)	Accessibility;
5)	Non-discrimination;
6)	Human rights;
7)	Improvement of environmental and industrial hygiene;
8)	Inherent dignity of the human person;
9)	Free consent;
10)	Care and education of children;
11)	Protection of children;
12)	Equality of men and women;
13)	Maintenance of peace.

Table 12 International Covenant on Economic, Social and Cultural Rights Ethical Principles.

International Covenant on Civil and Political Rights

The International Covenant on Civil and Political Rights is a core international human rights instrument of the United Nations, adopted through a 1966 UN General Assembly resolution.[22] The following core ethical requirements are enshrined in it:

International Covenant on Civil and Political Rights Ethical Principles	
1)	Prohibition of arbitrary or unlawful interference with privacy;
2)	Liberty and security of person;
3)	Fair and public hearings;
4)	Non-discrimination;
5)	Respect for, and observance of, human rights and freedoms;

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[22] International Covenant on Civil and Political Rights (adopted by General Assembly resolution 2200A (XXI) on 16 December 1966) <https://www.ohchr.org/sites/default/files/ccpr.pdf> accessed 16 December 2024.

6)	Respect for the inherent dignity of the human person;
7)	Free and full consent;
8)	Right to an effective remedy;
9)	Right for case review;
10)	Public safety and public health;
11)	Lawfulness;
12)	Freedom of expression;
13)	Freedom of thought, conscience and religion;
14)	Protection of children;
15)	Equality of rights for men and women;
16)	Freedom, justice and peace.

Table 13 International Covenant on Civil and Political Rights Ethical Principles.

Convention on the Rights of the Child

The Convention on the Rights of the Child is a core international human rights instrument of the United Nations, adopted through the 1989 UN General Assembly resolution.[23] It includes the following core ethical requirements:

Convention on the Rights of the Child Ethical Principles	
1)	Protection of children;
2)	Prohibition of arbitrary or unlawful interference with privacy;
3)	Protection of national security and public safety, public order, public health and morals;
4)	Fairness of hearings;
5)	Non-discrimination;

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[23] Convention on the Rights of the Child (adopted by General Assembly resolution 44/25 on 20 November 1989) <https://www.ohchr.org/sites/default/files/crc.pdf> accessed 16 December 2024.

6)	Protection of human rights;
7)	Consideration of the dangers and risks of environmental pollution;
8)	Dignity and worth of the human person;
9)	Informed consent;
10)	Periodic review of the treatment of children placed by the competent authorities;
11)	Lawfulness;
12)	Proportionality;
13)	Diversity;
14)	Freedom of expression;
15)	Freedom of thought, conscience and religion;
16)	Protection and care of children;
17)	Freedom, justice and peace.

Table 14 Convention on the Rights of the Child Ethical Principles.

Convention on the Elimination of All Forms of Discrimination against Women

The Convention on the Elimination of All Forms of Discrimination against Women is a core international human rights instrument of the United Nations, adopted through a 1979 UN General Assembly resolution.[24] It reflects the following core ethical requirements:

Convention on the Elimination of All Forms of discrimination against Women Ethical Principles	
1)	Protection of women;
2)	Strengthening of international peace and security;
3)	Right to protection of health and to safety;

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[24] Convention on the Elimination of All Forms of Discrimination against Women (adopted by UN General Assembly, New York, on 18 December 1979) <https://www.ohchr.org/sites/default/files/cedaw.pdf> accessed 16 December 2024.

4)	Non-discrimination;
5)	Human rights;
6)	Human dignity;
7)	Free and full consent;
8)	Periodic review;
9)	Access to food, health, education, training, and opportunities for employment and other needs;
10)	Protection of children.

Table 15 Convention on the Elimination of All Forms of discrimination against Women Ethical Principles.

International Convention on the Elimination of All Forms of Racial Discrimination

The International Convention on the Elimination of All Forms of Racial Discrimination is a core international human rights instrument of the United Nations, adopted through a 1965 UN General Assembly resolution.[25] It outlines the following core ethical requirements:

International Convention on the Elimination of All Forms of Racial Discrimination Ethical Principles	
1)	Right to security of person;
2)	Equal access to public service;
3)	Confidentiality;
4)	Non-discrimination;
5)	Respect for human rights;
6)	Dignity of the human person;
7)	Express consent;

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[25] International Convention on the Elimination of All Forms of Racial Discrimination (adopted by General Assembly resolution 2106 (XX) on 21 December 1965) <https://www.ohchr.org/sites/default/files/cerd.pdf> accessed 16 December 2024.

8)	Effective protection and remedies;
9)	Review of policies, and to amend, rescind or nullify any laws and regulations which have the effect of creating or perpetuating racial discrimination wherever it exists;
10)	Right to public health, medical care, social security and social services;
11)	Freedom of thought, conscience and religion;
12)	Freedom of opinion and expression;
13)	Peace and security.

Table 16 International Convention on the Elimination of All Forms of Racial Discrimination Ethical Principles.

International Convention on the Protection of All Migrant Workers and Members of Their Families

The International Convention on the Protection of All Migrant Workers and Members of Their Families is a core international human rights instrument of the United Nations, adopted through a 1990 UN General Assembly resolution.[26] It encompasses the following core ethical principles:

International Convention on the Protection of All Migrant Workers and Members of Their Families Ethical Principles	
1)	Prohibition of arbitrary or unlawful interference with privacy;
2)	Protection of national security and public safety, order, health and morals;
3)	Fair and adequate compensation;
4)	Non-discrimination;
5)	Protection of human rights;
6)	Respect for the inherent dignity of the human person;
7)	Right to an effective remedy;

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[26] International Convention on the Protection of All Migrant Workers and Members of Their Families (adopted by General Assembly resolution 45/158 on 18 December 1990) <https://www.ohchr.org/sites/default/files/cmw.pdf> accessed 16 December 2024.

8)	Right for case review;
9)	Lawfulness;
10)	Freedom of thought, conscience and religion;
11)	Freedom of expression;
12)	Medical care;
13)	Rights of the child;
14)	Regard for the elimination of discrimination against women.

Table 17 International Convention on the Protection of All Migrant Workers and Members of Their Families Ethical Principles.

American Convention on Human Rights

The American Convention on Human Rights was signed at the Inter-American Specialized Conference on Human Rights in San José, Costa Rica, in 1969,[27] and reflects the following core ethical principles:

American Convention on Human Rights Ethical Principles	
1)	Prohibition of arbitrary or unlawful interference with privacy;
2)	Personal liberty and security;
3)	Protection of national security, public safety, order, health or morals;
4)	Right to a fair trial;
5)	Non-discrimination;
6)	Right to respect for physical, mental, and moral integrity;
7)	Protection of human rights;
8)	Respect for the inherent dignity of the human person;

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[27] American Convention on Human Rights (signed at the Inter-American Specialized Conference on Human Rights, San José, Costa Rica, 22 November 1969) <https://www.oas.org/en/iachr/mandate/basics/3.american convention.pdf> accessed 17 December 2024.

9)	Free and full consent;
10)	Right to effective recourse;
11)	Lawfulness;
12)	Freedom of conscience and religion;
13)	Freedom of thought and expression;
14)	Rights of the child;
15)	Protection of women.

Table 18 American Convention on Human Rights Ethical Principles.

Cairo Declaration on Human rights in Islam

The Cairo Declaration on Human rights in Islam was adopted by the Organisation of Islamic Cooperation (OIC) in 1990,[28] with its latest revision in 2020. It contains the following core ethical principles:

Cairo Declaration on Human Rights in Islam Ethical Principles	
1)	Right to privacy;
2)	Safety and security;
3)	Fairness of wages and compensation;
4)	Non-discrimination;
5)	Human dignity;
6)	Human integrity;
7)	Protection of human rights;
8)	Right to live in a clean environment;
9)	Consent;

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[28] Cairo Declaration on Human rights in Islam (Organisation of Islamic Cooperation (OIC), first adopted on 5 August 1990, latest revision on 28 November 2020) <http://hrlibrary.umn.edu/instree/cairodeclaration.html> accessed 17 December 2024.

10)	Protection of health;
11)	Redress to grievances;
12)	Lawfulness;
13)	Diversity;
14)	Medical and social care;
15)	Rights of the child;
16)	Equality of women to men in human dignity.

Table 19 Cairo Declaration on Human Rights in Islam Ethical Principles.

Arab Charter on Human Rights

The Arab Charter on Human Rights was adopted by the League of Arab States, was adopted in 2004 and entered into force in 2008.[29] It reflects the following core ethical principles:

Arab Charter on Human Rights Ethical Principles	
1)	Prohibition of arbitrary or unlawful interference with privacy;
2)	Right to liberty and security of person;
3)	Protection of national security, public safety, order, health or morals;
4)	Right to a fair trial;
5)	Accessibility of education;
6)	Confidentiality;
7)	Non-discrimination;
8)	Protection of human rights;
9)	Right to a healthy environment;
10)	Respect for the inherent dignity of the human person;

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[29] Arab Charter on Human Rights (League of Arab States, adopted on 22 May 2004, entered into force on 15 March 2008) <http://hrlibrary.umn.edu/instree/loas2005.html> accessed 17 December 2024.

11)	Openness towards others;
12)	Free and full consent;
13)	Right to an effective remedy;
14)	Right to self-determination and to control over natural wealth and resources;
15)	Lawfulness;
16)	Freedom of opinion and expression;
17)	Freedom of thought, conscience and religion;
18)	Rights of the child;
19)	Rights of women;
20)	International peace and security.

Table 20 Arab Charter on Human Rights Ethical Principles.

Declaration of Principles on Freedom of Expression and Access to Information in Africa

The Declaration of Principles on Freedom of Expression and Access to Information in Africa was adopted by the Africa Commission on Human and People's Rights in 2019,[30] containing the following core ethical requirements:

Declaration of Principles on Freedom of Expression and Access to Information in Africa Ethical Principles	
1)	Freedom of expression;
2)	Transparency;
3)	Privacy;
4)	Accountability;
5)	Protection of health, safety, environment;

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[30] Declaration of Principles on Freedom of Expression and Access to Information in Africa (Africa Commission on Human and People's Rights, adopted on 10 November 2019) <https://achpr.au.int/sites/default/files/files/2022-08/declarationofprinciplesonfreedomofexpressioneng2019.pdf> accessed 17 December 2024.

6)	Fairness;
7)	Access to information without discrimination;
8)	Confidentiality;
9)	Risk mitigation;
10)	Respect for all human rights;
11)	Open appointment processes for employees;
12)	Access to effective remedies;
13)	Promotion of diversity, including regarding women and children;
14)	Security;
15)	Integrity of professional examinations and recruitment processes;
16)	Accuracy of information;
17)	Right to exercise autonomy in relation to personal information;
18)	Human dignity.;
19)	Erasure and rectification;
20)	Consent;
21)	Effective monitoring and regular review of privacy rights;
22)	Lawfulness;
23)	Proportionality;
24)	Inclusiveness for internet access;
25)	Interoperability of platforms and facilities;
26)	Reusability of information.

Table 21 Declaration of Principles on Freedom of Expression and Access to Information in Africa Ethical Principles.

African Charter on the Rights and Welfare of the Child

The African Charter on the Rights and Welfare of the Child was adopted by the African Union, entering into force in 1999,[31] and encompasses the following core ethical requirements:

African Charter on the Rights and Welfare of the Child Ethical Principles	
1)	Protection of children;
2)	Prohibition of arbitrary or unlawful interference with privacy;
3)	Freedom, dignity, security;
4)	Non-discrimination;
5)	Respect for human rights;
6)	Respect for the environment;
7)	Informed consent;
8)	Monitoring mechanisms;
9)	Care regarding health, physical, mental, moral and social development;
10)	Lawfulness;
11)	Freedom of expression;
12)	Freedom of thought, conscience and religion;
13)	Safety.

Table 22 African Charter on the Rights and Welfare of the Child Ethical Principles.

Human Rights Declaration of the Association of Southeast Asian Nations

The Human Rights Declaration of the Association of Southeast Asian Nations was adopted by the Association of Southeast Asian Nations (ASEAN) in Phnom Penh, Cambodia, in 2012,[32] and includes the following core ethical requirements:

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[31] African Charter on the Rights and Welfare of the Child (African Union, entered into force 29 November 1999) <https://au.int/sites/default/files/treaties/36804-treaty-african_charter_on_rights_welfare_of_the_child.pdf> accessed 17 December 2024.

[32] Human Rights Declaration of the Association of Southeast Asian Nations (adopted in Phnom Penh, Cambodia, on 18 November 2012) <https://asean.org/wp-content/uploads/2021/09/2013_ASEAN-Human-Rights-Declaration.pdf> accessed 17 December 2024.

Human Rights Declaration of the Association of Southeast Asian Nations Ethical Principles	
1)	Prohibition of arbitrary or unlawful interference with privacy;
2)	Respect for human rights;
3)	Accountability;
4)	Right to personal liberty and security;
5)	Fairness;
6)	Non-discrimination;
7)	Right to a safe, clean and sustainable environment;
8)	Dignity;
9)	Free and full consent;
10)	Right to an effective and enforceable remedy;
11)	Protection of national security, public order, health, safety, morality and general welfare;
12)	Protection of personal data;
13)	Inclusivity of participants;
14)	Freedom of opinion and expression;
15)	Freedom of thought, conscience and religion;
16)	Medical care;
17)	Right to peace;
18)	Rights of women, children, the elderly, persons with disabilities, migrant workers, and vulnerable and marginalised groups.

Table 23 Human Rights Declaration of the Association of Southeast Asian Nations Ethical Principles.

Asia-Pacific Economic Cooperation Privacy Framework

The Asia-Pacific Economic Cooperation (APEC) Privacy Framework was adopted by the APEC forum in 2015,[33] containing the following core ethical principles:

Asia-Pacific Economic Cooperation Privacy Framework Ethical Principles	
1)	Protection of privacy;
2)	Accountability;
3)	National security, public safety, public policy;
4)	Fair treatment of personal information;
5)	Lawfulness;
6)	Accessible and affordable mechanisms to exercise choice in relation to the collection, use and disclosure of personal information;
7)	Confidentiality;
8)	Reducing risks;
9)	Non-discrimination;
10)	Integrity of personal information;
11)	Accurate, complete and up-to-date personal information to the extent necessary for the purpose of use;
12)	Right to rectification, completion, amendment or deletion of personal information;
13)	Promotion and enforcement of ethical and trustworthy information practices;
14)	Limitation of personal information collection to information relevant to the purposes of collection;
15)	Consent;

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[33] Asia-Pacific Economic Cooperation Privacy Framework (APEC, 2015) <https://www.apec.org/docs/default-source/publications/2017/8/apec-privacy-framework-(2015)/217_ecsg_2015-apec-privacy-framework.pdf?sfvrsn=1fe93b6b_1> accessed 17 December 2024.

16)	Periodic review and reassessment of security safeguards;
17)	Regard for health risks;
18)	Data protection;
19)	Proportionality of measures;
20)	Recognition of diversities;
21)	Promotion of interoperability amongst privacy instruments;
22)	Consideration for children in how information is displayed.

Table 24 Asia-Pacific Economic Cooperation Privacy Framework Ethical Principles.

Under European Law

Given the location of the IDEA4RC activities in the European Union, ethical principles recognised in the European jurisdiction are further detailed in this section.

Charter of Fundamental Rights of the European Union

Based on the EU's foundation upon indivisible, universal values of human dignity, freedom, equality and solidarity, the Charter of Fundamental Rights constitutes the primary legislative text on human rights in the Union.[34] The Charter recognises the following core ethical principles:

Charter of Fundamental Rights of the European Union Ethical Principles	
1)	Respect for the protection of human dignity;
2)	Right to the integrity of the person, whether physical or mental;
3)	Respect for private and family life;
4)	Protection of personal data;
5)	Freedom of thought, conscience and religion;
6)	Non-discrimination;

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[34] Charter of Fundamental Rights of the European Union (2012/C 326/02) (2012) OJ C 326/391 <https://eur-lex.europa.eu/eli/treaty/char_2012/oj/eng> accessed 13 December 2024.

7)	Right to liberty and security of person;
8)	Respect for health, safety, and dignity;
9)	Fair processing of data for specified purposes and based on consent;
10)	Right of access to data;
11)	Right to rectification of data;
12)	Confidentiality;
13)	Protection of human rights;
14)	Environmental protection;
15)	Sustainable development;
16)	Protection of intellectual property;
17)	Proportionality;
18)	Respect for cultural, religious and linguistic diversity;
19)	Freedom of expression;
20)	Right of access to preventive healthcare;
21)	Rights of the child;
22)	Equality between men and women;
23)	Resolve to share a peaceful future based on common values.

Table 25 Charter of Fundamental Rights of the European Union Ethical Principles.

General Data Protection Regulation

The GDPR constitutes the primary legislative instrument in the EU regarding personal data protection.[35] As such, it has translated numerous ethical principles into normative requirements,

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[35] Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such. data, and repealing Directive 95/46/EC (General Data Protection Regulation) (2016) OJ L 119/1 <https://eur-lex.europa.eu/eli/reg/2016/679/oj> accessed 13 December 2024.

the primary of which is privacy, since personal data protection is the realisation of the right to privacy, including the following:

General Data Protection Regulation Ethical Principles	
1)	Right to privacy;
2)	Lawfulness;
3)	Fairness;
4)	Transparency;
5)	Data minimisation;
6)	Data accuracy;
7)	Integrity and confidentiality;
8)	Accountability;
9)	Right to be informed;
10)	Right of access;
11)	Right to rectification;
12)	Right to erasure ('right to be forgotten');
13)	Right to restriction of processing;
14)	Right to data portability;
15)	Right to object;
16)	Right to not be subject to automated individual decision-making;
17)	Ensuring data security as a crucial component of confidentiality of personal data;
18)	Respect for human rights;
19)	Taking account of the risks of varying likelihood and severity for rights and freedoms posed by data processing;
20)	Safeguarding human dignity;

21)	Collection of personal data for specified, explicit, and legitimate purposes;
22)	Periodic review for personal data retention;
23)	Protection of health data;
24)	Right to data protection;
25)	Necessity and proportionality of measures;
26)	Diversity;
27)	Freedom of expression and information;
28)	Freedom of thought, conscience and religion;
29)	Non-discrimination;
30)	Interoperability of data;
31)	Quality and safety in health care and the workplace;
32)	Protection of children.

Table 26 Charter of Fundamental Rights of the European Union Ethical Principles.

European Health Data Space Regulation

The European Health Data Space ('EHDS') is the first common EU data space in a specific area to emerge from the European strategy for data.[36] The European Health Data Space, once in place, will be a milestone in modernising health services, creating a secure and privacy-preserving environment for the sharing and accessing of health data across the European Union. The Regulation recognised the following core ethical principles:

European Health Data Space Regulation Ethical Principles	
1)	Informed consent;
2)	Data privacy;

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[36] Regulation of the European Parliament and of the Council on the European Health Data Space and amending Directive 2011/24/EU and Regulation (EU) 2024/2847 (European Health Data Space Regulation) PE -CONS 76/24 <https://data.consilium.europa.eu/doc/document/PE-76-2024-INIT/en/pdf> accessed 5 February 2025.

3)	Data protection;
4)	Transparency, accountability and security in data processing;
5)	Patient safety;
6)	FAIR principles: findable, accessible, interoperable and reusable;
7)	Fair data processing;
8)	Confidentiality;
9)	Management of risks;
10)	Non-discrimination;
11)	Integrity of electronic health data;
12)	Completeness and accuracy of electronic health data;
13)	Deletion;
14)	Ensuring electronic health data are as open as possible and as closed as necessary;
15)	Promotion of trust in safe handling of electronic health data;
16)	Right to effective remedy;
17)	Purpose limitation;
18)	Review and monitoring for the review of electronic health data processing;
19)	Sustainable governance;
20)	Health;
21)	Proportionality;
22)	Inclusive and sustainable framework for multi-country secondary use;
23)	Patient care;
24)	Protection of fundamental rights;

25)	Respect for personal autonomy;
26)	Control over personal electronic health data in the context of healthcare;
27)	Dignity;
28)	Lawfulness;
29)	Intellectual property rights.

Table 27 European Health Data Space Regulation Ethical Principles.

Data Act

The Data Act is a 2023 EU Regulation, establishing harmonised rules on fair access to and use of data.[37] The Regulation addresses numerous challenges and opportunities presented by data in the EU, emphasising fair access and user rights while ensuring the protection of personal data, outlining many ethical requirements:

Data Act Ethical Principles	
1)	Transparency;
2)	Security;
3)	Data protection;
4)	Privacy;
5)	Health and safety of natural persons;
6)	Fair access to and use of data;
7)	Confidentiality;
8)	Risk management;
9)	Proportionality;
10)	Non-discrimination;

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[37] Regulation (EU) 2023/2854 of the European Parliament and of the Council of 13 December 2023 on harmonised rules on fair access to and use of data and amending Regulation (EU) 2017/2394 and Directive (EU) 2020/1828 (Data Act) (2020) OJ L 1/71 <https://eur-lex.europa.eu/eli/reg/2023/2854/oj/eng> accessed 5 February 2025.

11)	Data integrity;
12)	Fundamental rights;
13)	Respect for the environment;
14)	Sustainability;
15)	Data accuracy;
16)	Respect for autonomy, decision-making and choices of user;
17)	Right to erasure;
18)	Open interoperability;
19)	Trust in data;
20)	Explicit consent;
21)	Right to effective remedy / redress;
22)	Purpose limitation;
23)	Review of complaints;
24)	Monitoring activity;
25)	Control of data;
26)	Lawfulness;
27)	Intellectual property rights;
28)	Inclusive and fair data market;
29)	Due care in maintaining business continuity;
30)	Data reuse.

Table 28 Data Act Ethical Principles.

Digital Services Act

The Digital Services Act is a 2022 EU Regulation on a Single Market for Digital Services, regulating online intermediaries and platforms.[38] Also including numerous requirements with an ethical dimension:

Digital Services Act Ethical Principles	
1)	Transparency;
2)	Accountability;
3)	User safety;
4)	Due diligence obligations for safety and transparency;
5)	Risk mitigation;
6)	High level of privacy, safety and security;
7)	Respect for human dignity;
8)	Accessibility and accuracy of information;
9)	Protection of confidential information;
10)	Non-discrimination;
11)	Protection of autonomy of individuals;
12)	Trustworthy online environment;
13)	Consent;
14)	Right to effective remedy;
15)	Periodic review of strategies and policies;
16)	Public health;
17)	Data protection;
18)	Lawfulness;

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[38] Regulation (EU) 2022/2065 of the European Parliament and of the Council of 19 October 2022 on a Single Market For Digital Services and amending Directive 2000/31/EC (Digital Services Act) (2022) OJ L 277/1 <https://eur-lex.europa.eu/eli/reg/2022/2065/oj> accessed 17 December 2024.

19)	Protection of intellectual property;
20)	Proportionality;
21)	Freedom of expression and information;
22)	Interoperability of systems;
23)	Fundamental rights;
24)	Protection of the child;
25)	Gender equality.

Table 29 Digital Services Act Ethical Principles.

Artificial Intelligence Act

The AI Act is a 2024 EU Regulation that lays down harmonised rules on artificial intelligence and is the world's first comprehensive AI law,[39] further encompassing many ethical requirements:

Artificial Intelligence Act Ethical Principles	
1)	Risk-based classification;
2)	Transparency;
3)	Explainability;
4)	Human oversight;
5)	Data quality;
6)	System accuracy;
7)	Non-discrimination;
8)	Data protection;
9)	Privacy;

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[39] Regulation (EU) 2024/1689 of the European Parliament and of the Council of 13 June 2024 laying down harmonised rules on artificial intelligence and amending Regulations (EC) No 300/2008, (EU) No 167/2013, (EU) No 168/2013, (EU) 2018/858, (EU) 2018/1139 and (EU) 2019/2144 and Directives 2014/90/EU, (EU) 2016/797 and (EU) 2020/1828 (Artificial Intelligence Act) (2024) OJ L 1/144 <https://eur-lex.europa.eu/eli/reg/2024/1689/oj/eng> accessed 17 December 2024.

10)	Respect for human dignity and personal autonomy;
11)	Accountability;
12)	Confidentiality;
13)	Public health, safety, security;
14)	Fairness;
15)	Accessibility of information;
16)	Data set integrity;
17)	Environmental protection;
18)	Deletion of data;
19)	Openness of systems;
20)	Trustworthiness of high-risk AI systems;
21)	Informed consent;
22)	Effective redress;
23)	Specified purpose of activity;
24)	Regular systematic review and updating;
25)	Energy sustainability;
26)	Lawfulness;
27)	Intellectual property rights;
28)	Proportionality;
29)	Inclusive and diverse design and development of AI systems;
30)	Freedom of expression and information;
31)	Care measures to ensure proper AI functioning;
32)	Software interoperability;

33)	Protection of fundamental rights;
34)	Protection of children;
35)	Gender balance.

Table 30 Artificial Intelligence Act Ethical Principles.

Data Governance Act

The Data Governance Act is a 2022 EU Regulation on European data governance that aims to make more data available for reuse and facilitate data sharing.[40] It enumerates numerous requirements with an ethical dimension: as presented in the table below.

Data Governance Act Ethical Principles	
1)	Data altruism;
2)	Transparency;
3)	Accountability;
4)	Privacy;
5)	Respect for fundamental rights;
6)	Public and national security;
7)	Safety and public health;
8)	Fair, transparent and non-discriminatory access to services;
9)	Confidentiality;
10)	Account for risks;
11)	Integrity of the individual and of data;
12)	Maintenance of full and accurate records;
13)	Enhancing the agency of data subjects;

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[40] Regulation (EU) 2022/868 of the European Parliament and of the Council of 30 May 2022 on European data governance and amending Regulation (EU) 2018/1724 (Data Governance Act) (2022) OJ L 152/1 <https://eur-lex.europa.eu/eli/reg/2022/868/oj/eng> accessed 17 December 2024.

14)	Right of erasure or right 'to be forgotten';
15)	Right to rectification of inaccurate personal data;
16)	Open access;
17)	Trustworthy and secure data systems;
18)	Consent;
19)	Access to review of complaints;
20)	Data control;
21)	Data protection;
22)	Lawfulness;
23)	Intellectual property rights;
24)	Proportionality;
25)	FAIR data principles: findable, accessible, interoperable, reusable;
26)	Gender balance.

Table 31 Data Governance Act Ethical Principles.

Cybersecurity Act

The Cybersecurity Act is a 2019 EU Regulation on the European Union Agency for Cybersecurity and on information and communications technology cybersecurity certification,[41] encompassing a number of ethical requirements, including the following:

Cybersecurity Act Ethical Principles	
1)	Security;
2)	Risk management;

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[41] Regulation (EU) 2019/881 of the European Parliament and of the Council of 17 April 2019 on ENISA (the European Union Agency for Cybersecurity) and on information and communications technology cybersecurity certification and repealing Regulation (EU) No 526/2013 (Cybersecurity Act) (2019) OJ L 151/15 <https://eur-lex.europa.eu/eli/reg/2019/881/oj/eng > accessed 17 December 2024.

3)	Incident response;
4)	System resilience;
5)	Trust in ICT products, services, and processes;
6)	Transparency;
7)	Protection of privacy and personal data;
8)	Respect for inclusiveness;
9)	Accountability;
10)	Fairness
11)	Easily accessible information;
12)	Confidentiality;
13)	Non-discrimination;
14)	Data integrity;
15)	Open internet;
16)	Right to effective judicial remedy;
17)	Monitoring compliance;
18)	Protection of intellectual property rights;
19)	Proportionality;
20)	Interoperability of cybersecurity products and solutions;
21)	Safety;
22)	Protection of children;
23)	Gender balance.

Table 32 Cybersecurity Act Ethical Principles.

Digital Markets Act

The Digital Markets Act is a 2022 EU Regulation that aims to make the EU's markets in the digital sector fairer and more contestable,[42] reflecting the following core ethical requirements:

Digital Markets Act Ethical Principles	
1)	Fair competition;
2)	Accountability;
3)	Transparency;
4)	Compliance with data protection and privacy rules;
5)	Respect for fundamental rights;
6)	Public health and security;
7)	Fair, reasonable and non-discriminatory conditions of access;
8)	Confidentiality;
9)	Risk management;
10)	System integrity;
11)	Consent;
12)	Right to seek redress;
13)	Regular review of gatekeeper status;
14)	Exercising control;
15)	Lawfulness;
16)	Proportionality;
17)	Interoperability;
18)	Product safety;

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[42] Regulation (EU) 2022/1925 of the European Parliament and of the Council of 14 September 2022 on contestable and fair markets in the digital sector and amending Directives (EU) 2019/1937 and (EU) 2020/1828 (Digital Markets Act) (2022) OJ L 265/1 <https://eur-lex.europa.eu/eli/reg/2022/1925/oj/eng accessed 17 December 2024.

19)	Protection of children online.

Table 33 Digital Markets Act Ethical Principles.

Law Enforcement Directive

The Law Enforcement Directive is a 2016 EU Directive that protects the personal data of individuals involved in criminal proceedings, be it as witnesses, victims or suspects, regarding the processing of personal data by competent authorities for the purposes of the prevention, investigation, detection or prosecution of criminal offences or the execution of criminal penalties, and on the free movement of such data.[43] It encompasses the following core ethical requirements:

Law Enforcement Directive Ethical Principles	
1)	Ensuring lawful, fair, and transparent processing of personal data;
2)	Collection of personal data for specified, explicit and legitimate purposes and not processed in a manner that is incompatible with those purposes;
3)	Ensuring that personal data is adequate, relevant and not excessive in relation to the purposes for which they are processed;
4)	Ensuring that personal data is accurate and, where necessary, kept up to date;
5)	Keeping personal data in a form permitting identification of data subjects for no longer than is necessary for the purposes for which they are processed;
6)	Processing personal data in a manner that ensures appropriate security of the personal data;
7)	Establishment of appropriate time limits for the erasure of personal data or for a periodic review of the need for the storage of personal data;
8)	Right of access by the data subject, with limitations;
9)	Right to rectification or erasure of personal data and restriction of processing;

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[43] Directive (EU) 2016/680 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 by competent authorities for the purposes of the prevention, investigation, detection or prosecution of criminal offences or the execution of criminal penalties, and on the free movement of such data, and repealing Council Framework Decision 2008/977/JHA (2016) OJ L 119/89 <https://eur-lex.europa.eu/eli/dir/2016/680/oj/eng> accessed 17 December 2024.

10)	Implementing appropriate technical and organisational measures which are designed to implement data protection principles in an effective manner and to integrate the necessary safeguards into the processing;
11)	Right to respect for private and family life;
12)	Accountability;
13)	Confidentiality;
14)	Monitoring of risks;
15)	Non-discrimination;
16)	Integrity of personal data;
17)	Respect for human rights;
18)	Consent;
19)	Control over personal data.

Table 34 Law Enforcement Directive Ethical Principles.

International Standards

This section will further review the ethical principles encompassed in key international standards, including for AI, personal data protection and security.

ISO/IEC TR 24368:2022 Information technology — Artificial intelligence — Overview of ethical and societal concern

This technical report's focal point is the provision on principles, processes and methods to address ethical and societal concerns regarding the use of AI.[44] The report recognises the following core ethical principles:

ISO/IEC TR 24368:2022 Ethical Principles	
1)	Accountability;

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[44] ISO/IEC TR 24368:2022 Information technology — Artificial intelligence — Overview of ethical and societal concern <https://www.iso.org/obp/ui/en/ - iso:std:iso-iec:tr:24368:ed-1:v1:en> accessed 17 December 2024.

2)	Fairness;
3)	Non-discrimination;
4)	Transparency and explainability;
5)	Professional responsibility;
6)	Promotion of human values;
7)	Privacy;
8)	Safety and security;
9)	Human control of technology;
10)	Community involvement and development;
11)	Human-centred design;
12)	Respect for the rule of law;
13)	Respect for international norms of behaviour;
14)	Environmental sustainability;
15)	Labour practices;
16)	Access and sharing control (authentication);
17)	Defining, achieving, and maintaining confidentiality, integrity, availability, accountability, authenticity, and reliability;
18)	Respect for human rights;
19)	Human autonomy;
20)	Remedying erroneous or harmful AI decisions when challenge or appeal is not possible;
21)	Ethics review;
22)	Regard for health;
23)	Data protection;

24)	Inclusive, interdisciplinary, diverse and cross-sectoral approach.

Table 35 ISO/IEC TR 24368:2022 Ethical Principles.

ISO 26000:2010 Guidance on social responsibility

This standard provides guidance on social responsibility.[45] It includes the following core ethical principles:

ISO 26000:2010 Ethical Principles	
1)	Recognition of social responsibility and engagement of stakeholders;
2)	Integrating socially responsible behaviour;
3)	Accountability;
4)	Transparency;
5)	Ethical behaviour;
6)	Respect for stakeholder interests;
7)	Respect for the rule of law;
8)	Respect for international norms of behaviour;
9)	Respect for human rights;
10)	Ensuring a particular human rights focus on – due diligence; human rights risk situations; avoidance of complicity; resolving grievances; discrimination and vulnerable groups; civil and political rights; economic, social, and cultural rights; and fundamental principles and rights at work;
11)	Fair operating practices;
12)	Consumer data protection and privacy;
13)	Health and safety;
14)	Access;

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[45] ISO 26000:2010 Guidance on social responsibility <https://www.iso.org/standard/42546.html> accessed 17 December 2024.

15)	Protection of the environment;
16)	Accuracy of information;
17)	Openness about decisions;
18)	Regular review of actions and practices related to social responsibility;
19)	Sustainability;
20)	Diversity;
21)	Rights of the child;
22)	Gender equality.

Table 36 ISO 26000:2010 Ethical Principles,

ISO/IEC 27001:2022 Information security, cybersecurity and privacy protection – Information security management systems – Requirements

This standard focuses on managing information security for information security, cybersecurity and privacy protection.[46] It complements data protection regulations, in combination with which it assists organizations to address security and privacy concerns comprehensively. It outlines the following requirements with an ethical dimension:

ISO/IEC 27001:2022 Ethical Principles	
1)	Ensuring assessment and evaluation of the security of information systems;
2)	Privacy protection;
3)	System access;
4)	Confidentiality, integrity, availability;
5)	Risk management;
6)	Environmental protection;
7)	Information deletion;

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[46] ISO/IEC 27001:2022 Information security, cybersecurity and privacy protection – Information security management systems – Requirements <https://www.iso.org/standard/27001> accessed 17 December 2024.

8)	Corrective action;
9)	Control on systems;
10)	Data protection;
11)	Intellectual property rights;
12)	Proportionality.

Table 37 ISO/IEC 27001:2022 Ethical Principles.

ISO/IEC 27701:2019 Security techniques — Extension to ISO/IEC 27001 and ISO/IEC 27002 for privacy information management — Requirements and guidelines

This standard is a data privacy extension to ISO 27001, assisting organisations in establishing systems to support compliance with the GDPR and other global data privacy requirements.[47] It encompasses the following core ethical requirements:

ISO/IEC 27701:2019 Ethical Principles	
1)	Ensuring the regular review and validation of the compliance status with GDPR, and management of any risks;
2)	Promoting the continual improvement of the system to ensure privacy and confidentiality protection, while addressing any vulnerabilities;
3)	Accountability;
4)	Security;
5)	Accession, correction, erasure;
6)	Integrity of information;
7)	Accuracy and quality;
8)	Erasure of information;
9)	Consent;

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[47] ISO/IEC 27701:2019 Security techniques — Extension to ISO/IEC 27001 and ISO/IEC 27002 for privacy information management — Requirements and guidelines <https://www.iso.org/standard/71670.html> accessed 17 December 2024.

10)	Collection and processing for purpose of document;
11)	Control of information;
12)	Lawfulness.

Table 38 ISO/IEC 27701:2019 Ethical Principles.

IEEE Standard Model Process for Addressing Ethical Concerns during System Design

This standard aims to support organisations in creating ethical value through system design, helping them to strengthen their value proposition and avoid value harms.[48] It is applicable to all kinds of products and services, including AI systems, and recognises the following core ethical principles:

IEEE Standard Model Process for Addressing Ethical Concerns during System Design Ethical Principles	
1)	Openness of systems;
2)	Fairness;
3)	Transparency;
4)	Replicability of systems;
5)	Autonomy of individuals;
6)	Care in system design;
7)	System control;
8)	Inclusiveness of participants;
9)	Innovation;
10)	Perfection;
11)	Privacy;

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[48] IEEE Standard Model Process for Addressing Ethical Concerns during System Design (IEEE Std 7000™-2021, approved on 16 June 2021) <https://ieeexplore.ieee.org/document/9536679> accessed 17 December 2024.

12)	Sustainability;
13)	Trust;
14)	Aesthetics;
15)	Health;
16)	Safety;
17)	Security: through confidentiality, integrity, availability, and accuracy;
18)	Protection of human rights;
19)	Protection of human autonomy and moral agency;
20)	Ensuring review of algorithms for fairness in application to the target population of human users or human subjects;
21)	Ensuring clarity on the responsibilities of human beings;
22)	Ensuring that anthropomorphic representation of the system is regarded as a risk;
23)	Accountability;
24)	Prohibition of unfair discrimination;
25)	Dignity;
26)	Data deletion;
27)	Informed consent;
28)	Appropriate redress;
29)	Diversity, including elderly people, minors, racial minorities, differently abled people, and different language speaking populations;
30)	Interoperability of systems;
31)	Gender equality.

Table 39 IEEE Standard Model Process for Addressing Ethical Concerns during System Design Ethical Principles

Other Requirements / Guidelines

This final section analyses the ethical principles found in key normative documents beyond international and European conventions, regulations and standards. In spite of their more informal nature, these documents significantly impact the performance of research activities and ethical compliance and, are, thus, included in the analysis.

The European Code of Conduct for Research Integrity

The European Code of Conduct for Research Integrity has been designed to assist the research community in the European territory to self-regulate their research activity in accordance with applicable normative and ethical requirements. Its 2023 Revised Edition better reflects the need for promoting a set of principles and good practices and assigning responsibility to all stakeholders involved.[49] The Code recognises the following core ethical principles:

The European Code of Conduct for Research Integrity Ethical Principles	
1)	Reliability in ensuring the quality of research, reflected in the design, methodology, analysis, and use of resources;
2)	Honesty in developing, undertaking, reviewing, reporting, and communicating research in a transparent, fair, full, and unbiased way;
3)	Respect for colleagues, research participants, research subjects, society, ecosystems, cultural heritage, and the environment;
4)	Accountability for the research from idea to publication, for its management and organization, for training, supervision, and mentoring, and for its wider societal impacts;
5)	Supporting appropriate infrastructure for the generation, management, and protection of data and research materials in all their forms that are necessary for reproducibility, traceability, and accountability;
6)	Ethics and research integrity training;

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[49] The European Code of Conduct for Research Integrity (All European Academies (ALLEA), revised edition June 2023): <https://allea.org/wp-content/uploads/2023/06/European-Code-of-Conduct-Revised-Edition-2023.pdf> accessed 17 December 2024.

7)	Designing, carrying out, analysing, and documenting research in a careful, transparent, and well-considered manner;
8)	Taking account of relevant differences among research participants, such as age, gender, sex, culture, religion, worldview, ethnicity, geographical location, and social class;
9)	Sharing of results in an open, honest, transparent, and accurate manner, respecting confidentiality of data or findings when legitimately required to do so;
10)	Handling research participants and subjects and related data with respect and care, and in accordance with legal provisions and ethical principles;
11)	Having due regard for the health, safety, and welfare of the community, of collaborators, and others connected with their research;
12)	Taking responsibility for ensuring research integrity standards, oversight, training, and safeguards;
13)	Ensuring appropriate stewardship, curation, and preservation of all data, metadata, protocols, code, software, and other research materials for a reasonable and clearly stated period;
14)	Ensuring that access to data is as open as possible, as closed as necessary, and where appropriate in line with the FAIR principles (Findable, Accessible, Interoperable and Reusable) for data management;
15)	Transparency about how to access and gain permission to use data, metadata, protocols, code, software, and other research materials;
16)	Informing research participants about how their data will be used, reused, accessed, stored, and deleted;
17)	Inclusion in any contracts or agreements of equitable and fair provisions for the management of research results' use, ownership, and protection under intellectual property rights;
18)	Integrity of the research and its results;

19)	Maintaining confidentiality unless there is prior approval for disclosure;
20)	Trustworthiness of the research system;
21)	Proportionality;
22)	Promotion of equality, diversity, and inclusion;
23)	Gender sensitivity.

Table 40 The European Code of Conduct for Research Integrity Ethical Principles.

Code of Ethics for Data-Based Value Creation

The Code of Ethics for Data-Based Value Creation, developed by the Data Innovation Alliance in Switzerland, is oriented towards addressing ethical issues arising in the creation of services and products based on data.[50] It provides for the design and performance of any related activities throughout the data lifecycle, i.e. from the data generation and acquisition to data storage and management to data analysis and knowledge generation to the final products and services. The Code includes the following core ethical principles:

Code of Ethics for Data-Based Value Creation Ethical Principles	
1)	Harm avoidance for both individuals and communities, entailing data protection, security and sustainability;
2)	Justice, distributing benefits and burdens fairly, in accordance with the principles of fairness, equality and solidarity;
3)	Autonomy, relating to the values of freedom and dignity;
4)	Control, focusing on clear definitions and effectiveness;

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[50] Code of Ethics for Data-Based Value Creation (Swiss Alliance for Data-Intensive Services, 2020): Overview <https://data-innovation.org/wp-content/uploads/2021/01/w-che-EthicalCodex_A2_Poster_EN.pdf>; Basics <https://digitalcollection.zhaw.ch/server/api/core/bitstreams/c738d871-1e44-4ae2-92d5-e72350419772/content>; Recommendations <https://data-innovation.org/wp-content/uploads/2021/01/w-che-EthicalCodex_A4_Broschure_Empfehlungen_EN.pdf>; Implementation <https://data-innovation.org/wp-content/uploads/2021/01/w-che-EthicalCodex_A4_Broschure_Implementierung_EN.pdf>; Context <https://data-innovation.org/wp-content/uploads/2021/01/w-che-EthicalCodex_A4_Broschure_Context_EN.pdf> accessed 17 December 2024.

5)	Transparency, according to the target group in question;
6)	Accountability, defining clear responsibility allocation;
7)	Privacy;
8)	Control of risks;
9)	Protection against discrimination;
10)	Minimising negative effects on the environment;
11)	Building and maintaining trust in data-based products and services;
12)	Respect for data protection;
13)	Informed consent;
14)	Comprehensive monitoring;
15)	Purpose limitation;
16)	Lawfulness;
17)	Proportionality;
18)	Accessibility of data;
19)	Accuracy of data;
20)	Deletion of data;
21)	Open data;
22)	Use of diverse data sets to avoid bias;
23)	Data interoperability;
24)	Respect for human rights;
25)	Promotion of safety;
26)	Protection of children;
27)	Gender balance.

Table 41 Code of Ethics for Data-Based Value Creation Ethical Principles.

European Ethical Principles for Digital Health

Following the establishment of the framework for digital health in January 2022 by the EU, a set of 16 principles for ethics in digital health were established with the goal of improving mutual understanding among Member States and facilitating the discussions for a European Health Data Space.[51] The principles cover the following:

European Ethical Principles for Digital Health	
1)	Making AI explainable and without discriminatory bias;
2)	Easy and reliable retrieval of data in a commonly used format;
3)	Availability of services;
4)	Ensuring intuitive and ready-to-use services;
5)	Compliance with eco-design practices;
6)	Health;
7)	Accessibility of digital health services;
8)	Inclusivity of digital health services.

Table 42 European Ethical Principles for Digital Health.

FAIR Principles

The FAIR principles require that data and other results are Finable, Accessible, Interoperable, and Reusable.[52] Even though FAIR principles do not explicitly cover ethics, several principles related to ethics can arise as a result, inclduing:

Ethical Principles arising from the FAIR principles	
1)	Enhancing data sharing, facilitating data access and re-use;

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[51] European Ethical Principles for Digital Health (European Union, 26 January 2022) <https://www.coe.int/en/web/human-rights-and-biomedicine/access-to-digital-spaces-to-understand-and-use-health-services/-/highest_rated_assets/nTmcJLi8P0UU/content/union-europ%C3%A9enne-principes-europ%C3%A9ens-pour-l-%C3%A9thique-du-num%C3%A9rique-en-sant%C3%A9> accessed 17 December 2024.

[52] FAIR Principles (2016) <https://www.go-fair.org/fair-principles/> accessed 16 December 2024.

2)	Transparency;
3)	Sustainability and facilitation of reproducibility;
4)	Efficiency and quality;
5)	Recognition of contribution and allocation of intellectual property rights;
6)	Accountability and trust;
7)	Sharing of benefits.

Table 43 Ethical Principles arising from the FAIR principles.

<u>EEAS Joint Declaration on privacy and the protection of personal data</u>

The Joint Declaration on privacy and the protection of personal data of the European External Action Service was signed in 2022,[53] with the signatories committing to foster and further develop international policy discussions and cooperation regarding data protection and cross-border data flows with trust, both bilaterally and multilaterally, to promote this shared vision and increase convergence amongst their data protection frameworks. It encompasses the following core ethical requirements:

EEAS Joint Declaration on privacy and the protection of personal data Ethical Principles	
1)	Ensuring respect for individuals' right to privacy and the protection of personal data;
2)	Lawfulness;
3)	Fairness;
4)	Transparency;
5)	Purpose limitation;
6)	Data minimisation;
7)	Limited data retention;

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[53] Joint Declaration on privacy and the protection of personal data (European External Action Service, 23 February 2022) <https://www.eeas.europa.eu/eeas/joint-declaration-privacy-and-protection-personal-data_en> accessed 17 December 2024.

8)	Data security;
9)	Accountability;
10)	Right to access;
11)	Right to rectification;
12)	Right to deletion;
13)	Ensuring safeguards for automated decision-making such as transparency and the possibility to challenge the outcome;
14)	Ensuring safeguards for international transfers to enable cross-border data flows by ensuring that the protection travels with the data;
15)	Ensuring independent oversight by a dedicated supervisory authority and effective redress;
16)	Strengthening trust in the digital environment.

Table 44 EEAS Joint Declaration on privacy and the protection of personal data Ethical Principles.

Ethics by Design and Ethics of Use Approaches for Artificial Intelligence

This 2021 Guidance was drafted by a panel of experts at the request of DG Research and Innovation of the European Commission, and aims at raising awareness in the scientific community, particularly with beneficiaries of EU research and innovation projects.[54] It offers guidance for adopting an ethically focused approach while designing, developing, and deploying and/or using AI based solutions, and recognises the following core ethical requirements:

Ethics by Design and Ethics of Use Approaches for Artificial Intelligence	
1)	Respect for human agency;
2)	Privacy, personal data protection and data governance;
3)	Fairness in rights and opportunities;

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[54] European Commission, 'Ethics by Design and Ethics of Use Approaches for Artificial Intelligence' (25 November 2021) <https://ec.europa.eu/info/funding-tenders/opportunities/docs/2021-2027/horizon/guidance/ethics-by-design-and-ethics-of-use-approaches-for-artificial-intelligence_he_en.pdf> accessed 19 December 2024.

4)	Individual, social and environmental well-being;
5)	Transparency;
6)	Accountability and oversight;
7)	Strong security measures;
8)	Ensuring safety and compliance;
9)	Accessibility of AI systems;
10)	Confidentiality;
11)	Risk mitigation;
12)	Inclusive, fair, and non-discriminatory AI agendas;
13)	Personal integrity;
14)	Respect for human rights;
15)	Ensuring data accuracy and representativeness;
16)	Protection of human dignity;
17)	Deletion of personal data;
18)	Openness of communication;
19)	Trust in data sharing;
20)	Rectification of datasets;
21)	Monitoring conformance;
22)	Mindfulness of environmental sustainability;
23)	Control of systems;
24)	Compliance with health and safety regulation;
25)	Lawfulness;
26)	Promotion of diversity, including gender.

Table 45 Ethics by Design and Ethics of Use Approaches for Artificial Intelligence.

European Commission Ethics Guidelines for Trustworthy AI

The Ethics Guidelines for Trustworthy AI were written by the Independent High-Level Expert Group on Artificial Intelligence, set up by the European Commission, and were made public in 2019.[55] The aim of the Guidelines is to promote Trustworthy AI, through being lawful, ethical, and robust, encompassing the following core ethical principles:

European Commission Ethics Guidelines for Trustworthy AI Ethical Principles	
1)	Respect for human autonomy;
2)	Prevention of harm;
3)	Fairness;
4)	Explicability;
5)	Risk-mitigation measures;
6)	Human agency and oversight;
7)	Technical robustness and safety;
8)	Privacy and data governance;
9)	Transparency;
10)	Diversity, non-discrimination;
11)	Environmental and societal well-being;
12)	Accountability;
13)	Accessibility of AI systems;
14)	Confidentiality;
15)	Trust, including personal integrity;
16)	Respect for human rights, human dignity;

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[55] European Commission, Ethics Guidelines for Trustworthy AI (Independent High-Level Expert Group on Artificial Intelligence, set up by the European Commission, made public on 8 April 2019) <https://www.europarl.europa.eu/cmsdata/196377/AI_HLEG_Ethics_Guidelines_for_Trustworthy_AI.pdf> accessed 19 December 2024.

17)	Accuracy of systems;
18)	Openness of systems;
19)	Consent;
20)	Review and redress mechanisms;
21)	Sustainability;
22)	Human control;
23)	Health and well-being;
24)	Data protection;
25)	Lawful AI;
26)	Proportionality;
27)	Inclusive design processes;
28)	Freedom of expression;
29)	Due care on what should not be done with AI;
30)	Human intervention;
31)	Resilience to attack and security;
32)	Protection of children;
33)	Gender balance;
34)	Promotion of peace.

Table 46 European Commission Ethics Guidelines for Trustworthy AI Ethical Principles.

European Commission 2030 Digital Compass: The European Way for the Digital Decade

'2030 Digital Compass: The European Way for the Digital Decade' is a 2021 Communication of the European Commission aiming to pursue digital policies that empower people and businesses to seize a human centred, sustainable and more prosperous digital future.[56] The Communication outlines the following core ethical requirements:

European Commission 2030 Digital Compass: The European Way for the Digital Decade Ethical Principles	
1)	Secure and trusted digital spaces;
2)	Ethical algorithmic decision-making;
3)	Protection of personal data and privacy;
4)	Freedom of expression, including access to diverse, trustworthy and transparent information;
5)	Freedom to set up and conduct a business online;
6)	Right to be forgotten;
7)	Protection of the intellectual creation of individuals in the online space;
8)	Universal access to internet services;
9)	Universal digital education and skills;
10)	Access to digital systems and devices that respect the environment;
11)	Accessible and human-centric digital public services and administration;
12)	Ethical principles for human-centric algorithms;
13)	Protection and empowerment of children in the online space;
14)	Access to digital health services;
15)	Fair sharing of data in the data economy;
16)	Assessing and addressing high-risk dependencies;

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[56] Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions, 2030 Digital Compass: The European Way for the Digital Decade (COM (2021) 118 final, 9 March 2021) <https://commission.europa.eu/system/files/2021-09/communication-digital-compass-2030_en.pdf> accessed 19 December 2024.

17)	Non-discriminatory access to online services;
18)	Ensuring full respect of EU fundamental rights;
19)	Openness of data;
20)	Promotion of targeted actions for effective remedies;
21)	Enhanced monitoring system;
22)	Sustainability;
23)	User-controlled identity;
24)	Inclusive digital society;
25)	Interoperability of data;
26)	Safety;
27)	Rights of the child;
28)	Prevention of gender imbalance.

Table 47 European Commission 2030 Digital Compass: The European Way for the Digital Decade Ethical Principles

OECD Privacy Principles

The Privacy Principles were published by the Organisation for Economic Co-operation and Development (OECD) in 2010, providing at the time the most used privacy framework internationally, serving as the basis for the creation of leading practice privacy programmes and additional principles.[57] The principles outline the following core ethical requirements:

OECD Privacy Principles	
1)	Collection limitation of personal data, by lawful and fair means;
2)	Data quality;
3)	Purpose specification for data collection and use;

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[57] OECD Privacy Principles (9 August 2010) <http://oecdprivacy.org/> accessed 20 December 2024.

4)	Use limitation;
5)	Security safeguarding, with risk protection for personal data;
6)	Openness about developments, practices and policies with respect to personal data;
7)	Individual participation;
8)	Accountability;
9)	Privacy;
10)	Consent;
11)	Accuracy of personal data;
12)	Right to challenge and, if successful, to have data erased, rectified, completed, or amended.

Table 48 OECD Privacy Principles.

OECD AI Principles

The AI Principles were adopted by the Organisation for Economic Co-operation and Development (OECD) in 2019 and updated in 2024, comprising the first intergovernmental standard on artificial intelligence.[58] They promote innovative, trustworthy AI that respects human rights and democratic values, encompassing the following core ethical principles:

OECD AI Principles	
1)	Inclusive growth, sustainable development and well-being;
2)	Human rights and democratic values;
3)	Fairness of AI systems;
4)	Privacy;
5)	Transparency;

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[58] OECD AI Principles (22 May 2019) <https://www.oecd.org/en/topics/ai-principles.html> accessed 20 December 2024.

6)	Explainability of AI systems;
7)	Robustness, security and safety;
8)	Accountability;
9)	Trustworthy AI;
10)	Environmental sustainability;
11)	Inclusion of underrepresented populations;
12)	Non-discrimination;
13)	Dignity and autonomy of individuals;
14)	Data protection;
15)	Diversity;
16)	Risk management;
17)	Bolstering information integrity while ensuring respect for freedom of expression;
18)	Intellectual property rights;
19)	Reducing gender inequality.

Table 49 OECD AI Principles.

UNESCO Recommendation on the Ethics of Artificial Intelligence

The Recommendation on the Ethics of Artificial Intelligence was adopted by the United Nations Educational, Scientific and Cultural Organization in 2021 and published in 2022.[59] It approaches AI ethics as a systematic normative reflection, based on a holistic, comprehensive, multicultural and evolving framework of interdependent values, principles and actions that can guide societies in dealing responsibly with the known and unknown impacts of AI technologies on human beings, societies and the environment and ecosystems, and offers them a basis to accept or reject AI technologies. The Recommendation outlines the following core ethical principles:

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[59] Recommendation on the Ethics of Artificial Intelligence (adopted by UNESCO on 23 November 2021) <https://unesdoc.unesco.org/ark:/48223/pf0000381137> accessed 20 December 2024.

UNESCO Recommendation on the Ethics of Artificial intelligence	
1)	Respect, protection and promotion of human rights and fundamental freedoms and human dignity;
2)	Environment and ecosystem flourishing;
3)	Ensuring diversity and inclusiveness;
4)	Living in peaceful, just and interconnected societies;
5)	Proportionality and Do Not Harm;
6)	Safety and security;
7)	Fairness;
8)	Non-discrimination;
9)	Sustainability;
10)	Right to privacy, and data protection;
11)	Human oversight and determination;
12)	Transparency and explainability;
13)	Responsibility and accountability;
14)	Awareness and literacy of AI systems;
15)	Multi-stakeholder and adaptive governance and collaboration;
16)	Accessibility of AI technologies;
17)	Risk prevention, mitigation and monitoring measures;
18)	Trustworthiness and integrity of AI systems;
19)	Autonomy, agency, worth and dignity of the individual;
20)	Promotion of open data;
21)	Informed consent;

22)	Effective remedies;
23)	Regular review of AI systems;
24)	Control of personal data;
25)	Health;
26)	Lawfulness;
27)	Freedom of expression;
28)	Care for vulnerable persons;
29)	System interoperability;
30)	Human intervention;
31)	Protection of children;
32)	Protection of girls and women.

Table 50 UNESCO Recommendation on the Ethics of Artificial intelligence.

IEEE General Principles of Ethically Aligned Design

The General Principles of Ethically Aligned Design were published by the IEEE Global Initiative on Ethics of Autonomous and Intelligent Systems, articulating high-level ethical principles that apply to all types of autonomous and intelligent systems (A/IS) and defining imperatives for their design, development, deployment, adoption, and decommissioning.[60] The principles encompass the following core ethical requirements:

IEEE General Principles of Ethically Aligned Design	
1)	Respect for human rights;
2)	Well-being;
3)	Data agency;
4)	Effectiveness of design;

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[60] IEEE General Principles of Ethically Aligned Design (2016) <https://standards.ieee.org/wp-content/uploads/import/documents/other/ead1e_general_principles.pdf> accessed 23 December 2024.

5)	Transparency;
6)	Accountability;
7)	Awareness of misuse;
8)	Competence for safe and effective operation;
9)	Privacy;
10)	Safety and security;
11)	Risk mitigation;
12)	Data access;
13)	Prioritising benefits to humanity and the natural environment;
14)	Data accuracy;
15)	Safeguarding people's agency;
16)	Respect for human dignity;
17)	Respect for cultural diversity;
18)	Trustworthiness;
19)	Consent;
20)	Maintaining people's capacity to have control over their identity;
21)	Protection of minors.

Table 51 IEEE General Principles of Ethically Aligned Design

Asilomar AI Principles

The Asilomar AI Principles were coordinated by the Future of Life Institute and developed at the Beneficial AI 2017 conference.[61] They comprise one of the earliest and most influential sets of AI governance principles, enumerating the following ethics and values:

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[61] Asilomar AI Principles (Future of Life Institute, 11 August 2017) <https://futureoflife.org/open-letter/ai-principles/> accessed 23 December 2024.

Asilomar AI Principles	
1)	Safety, including security;
2)	Failure transparency;
3)	Judicial transparency;
4)	Responsibility for design of AI systems;
5)	Value alignment;
6)	Human values, through compatibility with ideals of human dignity, rights, freedoms, and cultural diversity;
7)	Personal privacy, with the right to access, manage and control the data generated;
8)	Liberty and privacy;
9)	Shared benefit of systems;
10)	Shared prosperity;
11)	Human control;
12)	Non-subversion, maintaining respect and improvement for the social and civic processes on which the health of society depends;
13)	Avoidance of AI arms race;
14)	Fairness;
15)	Fostering a culture of cooperation, trust, and transparency;
16)	Care in planning and managing advanced AI;
17)	Risk planning and mitigation efforts.

Table 52 Asilomar AI Principles.

Paris Call for Trust and Security in Cyberspace Principles

The 2018 Paris Call for Trust and Security in Cyberspace was a call to come together to face new threats endangering citizens and infrastructure, based around nine common principles to secure cyberspace.[62] These principles have regard for the following requirements with ethical dimensions:

Paris Call for Trust and Security in Cyberspace Principles	
1)	Protect individuals and infrastructure;
2)	Protect the internet;
3)	Defend electoral processes;
4)	Defend intellectual property;
5)	Non-proliferation;
6)	Lifecycle security;
7)	Cyber hygiene, through maintaining the health and security of cyber activity;
8)	No private hack back, through preventing non-State actors from hacking-back.
9)	Promotion of international norms;
10)	Transparency;
11)	Accountability in the cyberspace;
12)	Protection of confidential information;
13)	Risk assessment;
14)	Integrity of the public core of the internet;
15)	Building trust;
16)	External review of source code, software updates and threat detection rules.;
17)	Internet monitoring;
18)	Data protection;

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[62] Paris Call for Trust and Security in Cyberspace Principles (12 November 2018) <https://pariscall.international/en/principles> accessed 23 December 2024.

19)	Data care;
20)	Reusability of software;
21)	Public safety.

Table 53. Paris Call for Trust and Security in Cyberspace Principles.

IRPC Charter of Human Rights and Principles for the Internet

The Charter of Human Rights and Principles for the Internet was published as its fourth edition in 2014 by the Internet Rights and Principles Coalition (IRPC), an international network of individuals and organizations working to uphold human rights in the online environment and across the spectrum of internet policy-making domains.[63] The Charter contains the following core ethical principles:

IRPC Charter of Human Rights and Principles for the Internet	
1)	Right to access to the internet;
2)	Right to non-discrimination in internet access, use and governance;
3)	Right to liberty and security on the internet;
4)	Right to development through the internet;
5)	Freedom of expression and information on the internet;
6)	Freedom of religion and belief on the internet;
7)	Freedom of online assembly and association;
8)	Right to privacy on the internet;
9)	Right to digital data protection;
10)	Right to education on and about the internet;
11)	Right to culture and access to knowledge on the internet;

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[63] The Charter of Human Rights and Principles for the Internet (International Rights and Principles Coalition, August 2014) available at <https://www.ohchr.org/sites/default/files/Documents/Issues/Opinion/Communications/InternetPrinciplesAndRightsCoalition.pdf> accessed 19 December 2024.

12)	Right to online participation in public affairs;
13)	Rights to consumer protection on the internet;
14)	Rights to health and social services on the internet;
15)	Responsibility, and ensuring refrain from violating human rights;
16)	Transparency;
17)	Openness, inclusiveness, and accountability;
18)	Fair information practices;
19)	Standards of confidentiality and integrity of IT-systems;
20)	Environmental sustainability;
21)	Respect for human dignity;
22)	Right to access, retrieve and delete personal data;
23)	Promotion of diversity;
24)	Informed consent;
25)	Right to an effective remedy;
26)	Deletion of data when it is no longer necessary for the purposes for which it was collected;
27)	Monitoring by independent data protection authorities;
28)	Control over personal data collection, retention, processing, disposal and disclosure;
29)	Lawfulness;
30)	Intellectual property protection;
31)	Proportionality;
32)	Interoperability of communication infrastructures and protocols;

33)	Right of children to grow up and develop in a safe environment free from sexual or other kinds of exploitation;
34)	Gender equality.

Table 54. IRPC Charter of Human Rights and Principles for the Internet.