Supporting eosc

Skills 4 eosc

D3.7 - Coordinated set of guides, fact-sheets and FAQs on ELSI aspects for Civil Servants and Policy Makers

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Deliverable Abstract

In order to contribute to the Training Material from Task 3.1, the Science4Policy Kit from Task 3.3 and the Workshops "The Practice of Informing Policy Through Evidence" from T3.5, this Deliverable 3.7 provides training materials in the form of guides, fact-sheets and FAQs on ELSI aspects including but not limited to ethical issues, Intellectual Property Rights, Public Sector Information and Research Data, Licensing, Database Sui Generis Rights and Personal Data Protection. This first version focuses on general issues and that may be of interest to both Civil Servants and policy makers, amongst other relevant profiles, like researchers, data stewards and legal and ethical advisors.

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Laws and Treaties

AIA	Artificial Intelligence Act
CDSM	Directive on Copyright and Related Rights in the Digital Single Market (Directive 2019/790)
DA	Data Act
DGA	Data Governance Act
DMA	Digital Markets Act
DSA	Digital Services Act
GDPR	General Data Protection Regulation (Regulation 2016/679)
IPRs	Intellectual Property Rights
InfoSoc	Directive on the harmonisation of certain aspects of copyrights and related rights in the information society
ODD	Open Data Directive (Directive 2019/1024)
TRIPS	Agreement on Trade-Related Aspects of Intellectual Property Rights
WCT	WIPO Copyright Treaty
WPPT	WIPO Performances and Phonograms Treaty

Contents

1 Introduction

1.1 Background: Challenges facing Policy Makers and Civil Servants in the connected age

Over the recent years, policy makers and Civil Servants working in the digital reality have been facing unprecedented pressure. Power dynamics in connected societies have been increasingly influenced by the omnipresence of data-driven processes, the growing complexity of digital environments, as well as by society's increasing dependency on data-driven services.[1] These processes have been, on the one hand, affecting competition by solidifying the market dominance of strong actors,[2] while at the same time paving the way for power to spill over further into democratic governance, giving rise to warnings on the risk of weakening public policymaking and privatization of the public sphere.[3]

Tangible manifestations of these dynamics include:

- A growing asymmetry of knowledge and understanding between technology companies and other actors in society, also linked to inequality in access to knowledge.
- Technological change and proprietisation of knowledge driving increasing obscurity,[4] necessitating intermediation[5] in exercise of rights.

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1 Peter Rott, Orla Lynskey, A Universal Service Framework for Powerful Online Platforms in: Helberger, Micklitz et al. [2021] Structural asymmetries in digital consumer markets, BEUC, 146, available at https://www.beuc.eu/sites/default/files/publications/beuc-x-2021-018_eu_consumer_protection_2.0.pdf Accessed 02 Aug 2024.

2 Amaral, M. (2021), "Case 1. Data-driven markets: regulatory challenges and regulatory approaches", in Case Studies on the Regulatory Challenges Raised by Innovation and the Regulatory Responses, OECD Publishing, Paris, https://doi-org.kuleuven.e-bronnen.be/10.1787/e1cf78cd-en. Accessed 02 Aug 2024.

3 Hans-W. Micklitz, Dissolution of EU Consumer Law Through Fragmentation and Privatisation in: Natali Helberger, Betül Kas, Hans-W. Micklitz, Monika Namysłowska, Laurens Naudts, Peter Rott, Marijn Sax, Michael Veale [2024] *Digital Fairness for Consumers,* BEUC 69, available at https://www.beuc.eu/sites/default/files/publications/BEUC-X-2024-032_Digital_fairness_for_consumers_Report.pdf, accessed 02 Aug 2024.

4 Forbrukerrådet (2020) Out of control. How consumers are exploited by the online advertising industry, accessible at https://storage02.forbrukerradet.no/media/2020/01/2020-01-14-out-of-control-final-version.pdf , accessed 02 Aug 2024.

5 See eg. Hans-W. Micklitz (2023) The Role of Standards in Future EU Digital Policy Legislation A Consumer Perspective, ANEC, https://www.anec.eu/images/Publications/other-publications/2023/ANEC-DIGITAL-2023-G-138.pdfa

- Increasingly apparent utility limits of informed consent as a policy tool.
- Disempowerment of the individual data subject/consumer/citizen (on a level of own perception [e.g. not filing complaints due to 'low chance of success']⁶ but also factually, e.g. in terms of burden of proof).
- Weak accountability and insufficient compliance pull of EU laws towards powerful actors, with cases of compliance correlating with tangible business interest⁷.
- Insufficient alternatives to mainstream commercial frameworks (e.g. free and open-source software)
- Fast technological change increasing risk of early obsolescence of targeted regulation
- A growing imbalance in representation of interests (industry v. civil society) in policymaking.

As representatives of the public interest, Policy Makers and Civil Servants working in policy-related areas need the capacity to perform their public administration roles along with their mission to strengthen and protect the democratic society. Whether their role entails

- **collaborating with researchers** (e.g. by commissioning research studies) or
- **engaging in research activities** directly -

- integrating Open Science ("**OS**") programs and practices forms an important element in fulfilling that mission.

For decision makers in the policy context, understanding, promoting, supporting and implementing Open Science is interlinked with their broad substantive independence, particularly in terms of remaining unaffected by narratives of stakeholders representing commercial interests. This requires a broad awareness of the applicable regulatory environment as well as the social and market context.

The role of this document is to support this important task. Taking the Ethical, Legal and Social Issues (ELSI) perspective on the relevant legislation,

6 BEUC (2023) Connected but unfairly treated: Consumer survey results on the fairness of the online environment, 9. Available at https://www.beuc.eu/sites/default/files/publications/BEUC-X-2023-113_Fairness_of_the_digital_environment_survey_results.pdf.

7 For example, regarding content moderation, as at August 2, 2024, the DSA Transparency Database indicates a strong disproportion between numbers of Statements of Reasons between Google Shopping (over 2.1 billion) constituting over 85% of all SoRs. Source: https://transparency.dsa.ec.europa.eu/dashboard

this work serves as a compendium of relevant information to enable a comfortable level of understanding of matters of personal data protection, intellectual property rights, data regulation and ethics from the perspective of Civil Servants and Policy Makers.[8]

1.2 Links to relevant Minimum Viable Skillset career profiles

This section puts into practice the relevant MVS (Minimum Viable Skillset) profiles developed under the Skills4EOSC project as part of Deliverable 2.1 describing key skills and competences for a role involved in practicing Open Science with the support of the EOSC. MVS Profiles are synthesized from established competences frameworks and resources. They are proposed as an aid to skills development, especially curriculum and course design. Each MVS Profile relates a skillset to the Open Science (OS) practices, activities, and outcomes that may typically be expected of the role concerned.[9]

1.2.1 Interlinks with Policy Makers MVS (Research Policy, Evidence-based Policy Maker Roles)

Organisational context: In the broadest sense, Policy Makers are often appointed officials and government employees who are responsible and co-responsible for formulating policies and ensuring their objective quality in light of available data and evidence. The Policy Maker MVS profiles apply in particular to roles in the following organisational contexts:

- Ministries
- Governmental organisations
- National agencies
- National funding organisations
- Research Performing Organisations
- Data Protection Authorities

[8] The main assumptions and parameters for the creation of this document are based on the granular skillset profiles depending on the specific roles, as defined in the MVS (Minimum Viable Skillset) profiles developed under Work Package 2 of Skills4EOSC. See D2.1 Catalogue of Open Science Career Profiles - Minimum Viable Skillsets (zenodo.org).

[9] The methodology is further described in the main Skills4EOSC Deliverable 2.1 report. https://zenodo.org/records/8101903

In the context of Open Science,[10] Policy Maker roles necessitate creation of awareness and circumstances that foster the support of Open Science programs, and uptake of Open Science practice for effective policy making in service of the common good.

On a knowledge level, the following competences are particularly relevant to Policy Makers to operate on a required level of substantive independence:

- Good understanding of OS and its practices.
- Knowledge of the Findable, Accessible, Interoperable, and Reusable (FAIR) principles.
- Knowledge on Intellectual Property Rights and non-personal data management.
- Knowledge of the applicable ethical principles, frameworks and codes of conduct.
- Knowledge on legal issues related to personal data governance.
- Knowledge on data use agreements.

On a practical level, this includes:

- Creation of appropriate partnerships with key stakeholders
- Building a team of experts.

1.2.2 Interlinks with Civil Servants MVS

Organisational context: Under most circumstances, Civil Servants are government employees and are directly engaged in exercising executive power in a state. Civil Servants are responsible for carrying out a range of administrative, regulatory, or policy-related functions. Examples of civil service roles may include clerks, analysts, policy advisors, inspectors, and managers. Civil service employment is typically non-political, meaning that Civil Servants are expected to remain neutral and non-partisan in their work. This is important to ensure that government and public sector

[10] Open Science is a set of values, principles, and practices that aim to make scientific research from all fields accessible to everyone, for the benefit of the whole humanity. It prioritizes access to the products of scientific research (research articles, data, software) as well as participation and collaboration in the process of knowledge production (citizen science, indigenous knowledge systems) https://unesdoc.unesco.org/ark:/48223/pf0000379949. See also Section 3.2.2.1 – Copyright and Open Science. (citizen science, indigenous knowledge systems)

organizations operate fairly and effectively, without being influenced by political bias or favoritism.

Civil Servant roles in the context of Open Science necessitate acting in support of the public interest in particular via creating and supporting open access to scientific knowledge, data, and research results, appropriate reuse of research data.

In the Open Science context, Civil Servants can contribute to a broad range of outcomes[11] including working towards making research more transparent, accessible, and reproducible. Through practices such as fostering collaboration and knowledge sharing, making scientific knowledge and research results openly available, implementing policies to support open access publications and data, including reuse of relevant data in the decision-making context, Civil Servants can meaningfully contribute to implementation of Open Science principles.

On a knowledge level, the competences that enable Civil Servants to meaningfully contribute to Open Science outcomes, the following are particularly relevant:[12]

- Good understanding of OS principles and practices, open data, open research and open access
- Solid understanding of OS research ethics
- Capability to provide training and education to researchers, policymakers, and public citizens about OS practices
- Good understanding of data management, including data storing, analysis and sharing according to the FAIR and OS principles

1.3 Deliverable overview

The main objective of this Deliverable is to contribute to the "Open Science training for Policy Makers and Civil Servants" from Task 3.1, the "Science4Policy kit" from Task 3.3 and with the Workshops "The Practice of Informing Policy Through Evidence" from Task 3.5. This contribution will take the form of training materials: guides, fact-sheets and FAQs, as described below:

[11] Please refer to Skills4EOSC Deliverable 2.1. for a detailed overview.

[12] Id.

FAQs on the following topics:

- Personal Data Protection;
- Intellectual property and other non-personal data protection, including the following:
    - Intellectual Property (general aspects);
    - Copyright;
        - Intersection between Copyright and Open Science;
        - Licensing;
    - Sui Generis Database Rights;
    - Trade Secrets;
    - Non-personal data and Public Sector Bodies;
        - Data under the Open Data Directive;
        - Data under the Data Governance Act;
        - Data under EU-Funded Projects.

Appendix A: Fact Sheets:

- Scope of the GDPR;
- Legal basis and principles of the GDPR;
- Rights of the Data Subject;
- EU Legal Framework on Data (main Directives, Regulations and Proposals);
- Intellectual Property Rights:
- Relationship between Directives, National Laws and International Treaties.

Appendix B: Privacy Templates: How to write a Policy Privacy in a Research Project:[13]

- This Appendix comprises a set of 10 ready-made templates for drafting a legally compliant privacy policy in a research project.
- The templates are designed to prevent common errors and misconceptions in designing privacy policies, while remaining adaptable to specific circumstances.

For the Ethical issues, it is understandable that FAQs and Fact Sheets would not be the optimal format to share relevant information and the best practices on the matter. Hence a brief Guide was proposed addressing

[13] Used by permission from authors. The document is also available at How to write a Policy Privacy in a Research Project (zenodo.org). A version customized for the Skills4EOSC project is also available, please see Appendix B.

some of the main resources on ethical issues related to research and Open Science.

Finally, considering that a substantial amount of this Deliverable addresses legal issues and/or is based on legal resources, some clarifications must be made:

- The main legal resources used in this document are EU Directives and Regulations. However, it should be noted that matters concerning specific fields, like copyright, are nationally regulated and, even though there is some harmonisation throughout the EU, national law must be considered. Your organization practices may be subject to national laws, sectoral regulation and other obligations set forth in contracts;
- Therefore, this material should be considered for general informatory purposes only. It must not be interpreted as legal advice in any circumstance and should not be used as basis for any decision regarding legal and ethical issues. For legal advice and advice on ethics, you should contact the competent offices inside your organization (e.g. legal office and ethics committee).

2 Personal Data Protection

EU legislation, namely the General Data Protection Regulation (GDPR)[14] as well as other relevant directives, like the E-Privacy Directive (Directive 2002/58/EC), and the applicable laws, opinions and guidelines issued by the Supervisory Authorities, set up rules and mechanisms to ensure strong protection to personal data and counteract their unlawful and purposeless processing. The GDPR is directly legally applicable, i.e. it does not require implementing legislation at the national level, within the European Economic Area (EEA).

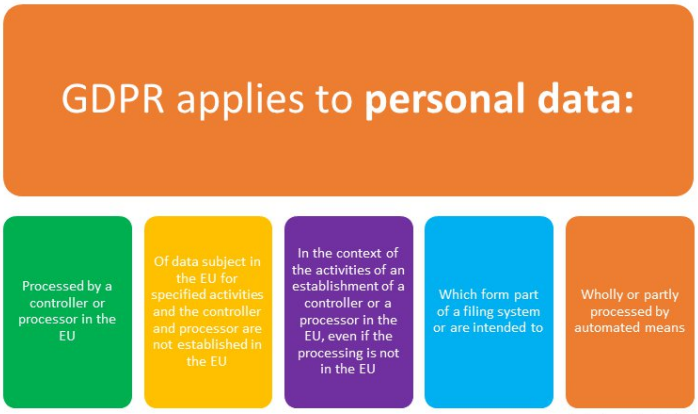
The GDPR ensures rights to data subjects but also imposes duties on natural and legal persons, public authorities, or other bodies (data controllers) while determining how to process personal data. In spite of its overarching goal of harmonisation, the GDPR allows Member States to enact more stringent restrictions as in the case of certain categories of data such as health and genetic data.

Considering the centrality of the GDPR to the EU Legal Framework on Personal Data Protection, the following sections will provide an FAQ and multiple Fact Sheets on some of the main aspects of the GDPR that may be helpful to the beneficiaries of the trainings carried out using this material.

2.1 Fact Sheets

Slides 3 to 6 of the document provided in Appendix A of this document and also in editable format in the Zenodo record (DOI: 10.5281/zenodo.12818168)

[14] 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), OJEU 4.5.2016, l.119/1.



Arts 2 and 3, GDPR

GDPR, art. 3 Territorial scope

1. This Regulation applies to the processing of personal data in the context of the activities of an establishment of a controller or a processor in the Union, regardless of whether the processing takes place in the Union or not.

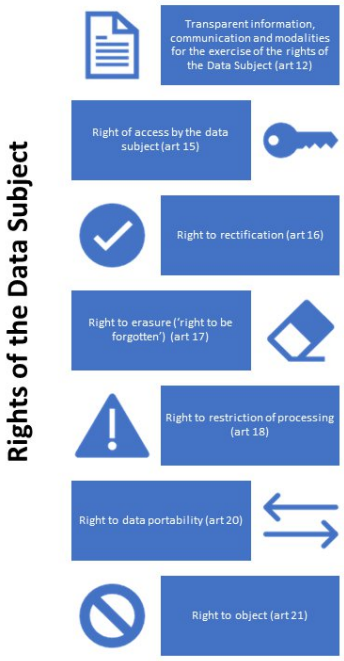
2. This Regulation applies to the processing of personal data of data subjects who are in the Union by a controller or processor not established in the Union, where the processing activities are related to: (a) the offering of goods or services, irrespective of whether a payment of the data subject is required, to such data subjects in the Union; or (b) the monitoring of their behaviour as far as their behaviour takes place within the Union. 3. This Regulation applies to the processing of personal data by a controller not established in the Union, but in a place where Member State law applies by virtue of public international law.

Scope of the GDPR
(material and territorial scopes)

GDPR, art. 2 Material scope

1. This Regulation applies to the processing of personal data wholly or partly by automated means and to the processing other than by automated means of personal data which form part of a filing system or are intended to form part of a filing system.
2. This Regulation does not apply to the processing of personal data: (a) in the course of an activity which falls outside the scope of Union law; (b) by the Member States when carrying out activities which fall within the scope of Chapter 2 of Title V of the TEU; (c) by a natural person in the course of a purely personal or household activity; (d) by competent authorities for the purposes of the prevention, investigation, detection or prosecution of criminal offences or the execution of criminal penalties, including the safeguarding against and the prevention of threats to public security.

Author: Valentina Colcelli and Sabrina Brizioli



Applicable Restrictions (art 23(1) and (2), GDPR)

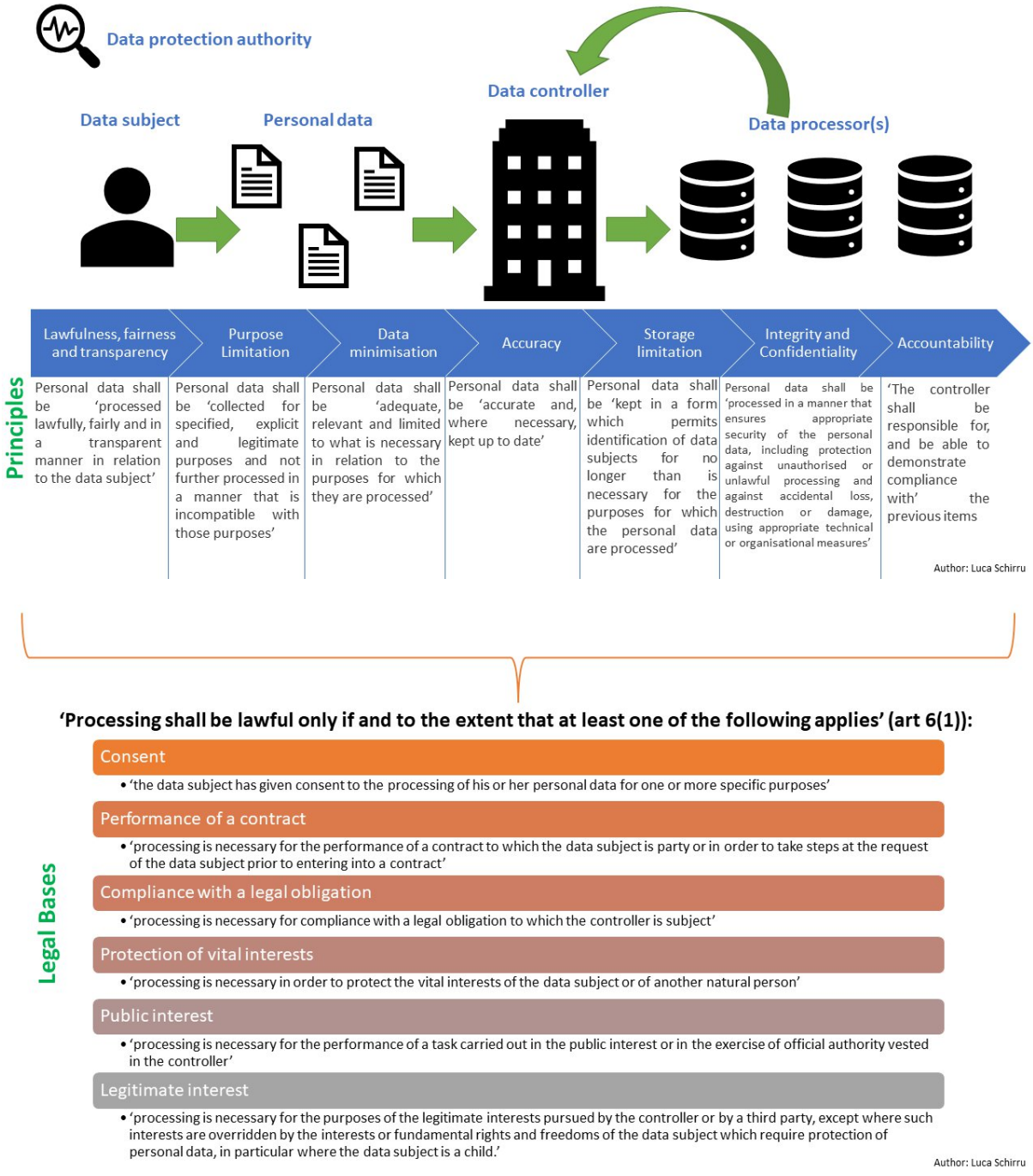
Union or Member State law to which the data controller or processor is subject may restrict by way of a legislative measure the scope of the obligations and rights [...] when such a restriction **respects the essence of the fundamental rights and freedoms and is a necessary and proportionate measure in a democratic society to safeguard**:

- national security;
- defence;
- public security;
- the prevention, investigation, detection or prosecution of criminal offences or the execution of criminal penalties, including the safeguarding against and the prevention of threats to public security;
- other important objectives of general public interest of the Union or of a Member State, in particular an important economic or financial interest of the Union or of a Member State, including monetary, budgetary and taxation a matters, public health and social security;
- the protection of judicial independence and judicial proceedings;
- the prevention, investigation, detection and prosecution of breaches of ethics for regulated professions;
- a monitoring, inspection or regulatory function connected, even occasionally, to the exercise of official authority in [selected] cases;
- the protection of the data subject or the rights and freedoms of others;
- the enforcement of civil law claims.

In particular, any legislative measure referred [above] shall contain specific provisions at least, where relevant, as to:

- the purposes of the processing or categories of processing;
- the categories of personal data;
- the scope of the restrictions introduced;
- the safeguards to prevent abuse or unlawful access or transfer;
- the specification of the controller or categories of controllers;
- the storage periods and the applicable safeguards taking into account the nature, scope and purposes of the processing or categories of processing;
- the risks to the rights and freedoms of data subjects; and
- the right of data subjects to be informed about the restriction, unless that may be prejudicial to the purpose of the restriction.

Author: Valentina Colcelli and Sabrina Brizioli


Data protection authority
Data controller
Data subject
Personal data
Data processor(s)
Principles
Lawfulness, fairness and transparency
Purpose Limitation
Data minimisation
Accuracy
Storage limitation
Integrity and Confidentiality
Accountability
Personal data shall be 'processed lawfully, fairly and in a transparent manner in relation to the data subject'
Personal data shall be 'collected for specified, explicit and legitimate purposes and not further processed in a manner that is incompatible with those purposes'
Personal data shall be 'adequate, relevant and limited to what is necessary in relation to the purposes for which they are processed'
Personal data shall be 'accurate and, where necessary, kept up to date'
Personal data shall be 'kept in a form which permits identification of data subjects for no longer than is necessary for the purposes for which the personal data are processed'
Personal data shall be 'processed in a manner that ensures appropriate security of the personal data, including protection against unauthorised or unlawful processing and against accidental loss, destruction or damage, using appropriate technical or organisational measures'
'The controller shall be responsible for, and be able to demonstrate compliance with' the previous items
Author: Luca Schirru
'Processing shall be lawful only if and to the extent that at least one of the following applies' (art 6(1)):
Legal Bases
Consent
• 'the data subject has given consent to the processing of his or her personal data for one or more specific purposes'
Performance of a contract
• 'processing is necessary for the performance of a contract to which the data subject is party or in order to take steps at the request of the data subject prior to entering into a contract'
Compliance with a legal obligation
• 'processing is necessary for compliance with a legal obligation to which the controller is subject'
Protection of vital interests
• 'processing is necessary in order to protect the vital interests of the data subject or of another natural person'
Public interest
• 'processing is necessary for the performance of a task carried out in the public interest or in the exercise of official authority vested in the controller'
Legitimate interest
• 'processing is necessary for the purposes of the legitimate interests pursued by the controller or by a third party, except where such interests are overridden by the interests or fundamental rights and freedoms of the data subject which require protection of personal data, in particular where the data subject is a child.'
Author: Luca Schirru

2.2 FAQ

What is the GDPR?

The General Data Protection Regulation is a personal data protection law that safeguards the privacy of European residents with respect to how their digital data is collected, stored, processed, shared, and used. In its own wording, it "lays down rules relating to the protection of natural persons with regard to the processing of personal data and rules relating to the free movement of personal data.)" (Art. 1(1) GDPR).

What does "processing" encompass?

"Processing", under the GDPR, encompasses "any operation or set of operations which is performed on personal data or on sets of personal data, whether or not by automated means, such as collection, recording, organisation, structuring, storage, adaptation or alteration, retrieval, consultation, use, disclosure by transmission, dissemination or otherwise making available, alignment or combination, restriction, erasure or destruction;" (Art. 4(2) GDPR).

What is "personal data"? (for GDPR purposes)

Personal data is understood as "any information relating to an identified or identifiable natural person ('data subject')" (Art. 4(1) GDPR).

What does "identifiable" means?

In order to be considered "identifiable" for the purposes of the regulation, a natural person may be "identified, directly or indirectly, in particular by reference to an identifier such as a name, an identification number, location data, an online identifier or to one or more factors specific to the physical, physiological, genetic, mental, economic, cultural or social identity of that natural person" (Art. 4(1) GDPR).

Do all kinds of personal data require the same treatment?

No. There are specific kinds of data that require special attention, as is the case of:

> personal data revealing racial or ethnic origin, political opinions, religious or philosophical beliefs, or trade union membership, and the processing of genetic data, biometric data for the purpose of uniquely identifying a natural person, data concerning health or data concerning a natural person's sex life or sexual orientation shall be prohibited (GDPR, Art. 9 (1)).

Another important type of data that requires special treatment is children's personal data, as provided in Recital 38 of the GDPR:

> Children merit specific protection with regard to their personal data, as they may be less aware of the risks, consequences and safeguards concerned and their rights in relation to the processing of personal data. Such specific protection should, in particular, apply to the use of personal data of children for the purposes of marketing or creating personality or user profiles and the collection of personal data with regard to children when using services offered directly to a child. The consent of the holder of parental responsibility should not be necessary in the context of preventive or counselling services offered directly to a child.

Is informed consent always necessary?

Informed and free consent may be necessary for legitimate processing of personal data, since it is one of the possible legal bases for processing personal data under the GDPR. According to the GDPR, informed consent must be free, specific, informed and unambiguous and, therefore, cannot be presumed.

Are there any specific considerations for processing data for research purposes?

Yes. For example, Art. 89 (2) GDPR creates "safeguards and derogations relating to processing for archiving purposes in the public interest, scientific or historical research purposes or statistical purposes". This enables derogations to be introduced in Union or national laws from some rights of the data subject such as the right to access their data, right of rectification of data or right to object to its processing – in so far as the exercise of such rights would preclude or seriously impair the achievement of such purposes.

What are the main aspects of processing personal data to consider in research?

When it comes to the GDPR, multiple aspects should be taken into account when research activities encompass the processing of personal data, including but not limited to: the data subject identified or identifiable, the involvement of targeted groups (e.g., volunteers, workers, teenagers or children, vulnerable adults, local communities), the categories of data processed, and the kind of processing (e.g. secondary processing).

What does secondary processing mean?

Further or secondary use of personal data that are not collected directly from the data subjects or that have been initially processed for other purpose(s) or research projects. When it comes to the use of personal data for other purposes, the new purpose must be compatible with the original one and the following aspects should be taken into account: a) the context of the data collection; b) the nature and type of the data; c) the impact and consequences of the further processing; d) the relationship between the original purpose and the new one; e) the necessary safeguards (e.g. pseudonymisation, encryption).

What does pseudonymisation imply and what are its effects?

As a safeguard and technical measure relevant within the GDPR, pseudonymisation makes the data subject unidentifiable unless the personal data is available with more information. This means that it is not sufficient to pseudonymise data but also to properly protect personal data in order to avoid re-identification by linking it with other/extra information. On the other hand, pseudonymisation makes easier the data sharing as long as appropriate measures are implemented to protect data.

Is the pseudonymisation process reversible?

The pesudonymisation process removes and replaces direct identifiers and makes not possible to identify a specific person without other/extra information. This implies that data can be still indirectly linked to the data subject and in this sense pseudonymised data can be considered personal data. Because of this, technical or organisational measures should be applied to keep the information separated and/or to avoid accidental or

unauthorised linkage with the data subject. Re-identification is possible and in this sense pseudonymisation differs from anonymisation that, in fact, delinks data from a specific individual by removing personal information useful to identify him/her. Anonymisation is the irreversible process that results in creation of non-personal data, whereas pseudonymisation does not prevent personal data from being linked back to the individual with further information.

What kind of security measures must be employed?

Some technical and organisational security measures must be applied to facilitate the data flow towards the European Union. This is furthermore important in those cases in which a project consortium receives data for further processing. Partners of a consortium should have a legitimate interest in transmitting personal data and the flow of data for purposes other than those for which they were initially collected, which should be allowed if the activities are compatible with the scope for which the data and information were initially collected.

What is new under the GDPR in the approach to personal data?

The GDPR requires data controllers and processors to be responsible, to take responsibility for the processing activities, and to be compliant to principles and adequate safeguards. For this, the GDPR introduced the accountability principle, which is rooted in the EU Charter of Fundamental Rights, specifically in Art. 8 (protection of personal data).

What does accountability mean?

Pursuant to Art. 5 of the GDPR, the controller shall be responsible for, and be able to demonstrate compliance with, the principles relating to the processing of personal data. This practically implies putting in place reliable and effective measures and records to demonstrate compliance with data protection rules.

How to be responsible and compliant to GDPR according to the accountability principle?

Being compliant with the accountability principle is not a theoretical activity. Responsibility should be achieved by being proactive and able to organize

effective data protection measures. Compliance essentially requires the ability to provide evidence that significant steps to protect personal data have been taken. Both responsibility and compliance, which are at the core of accountability, are pivotal to create a culture of commitment to data protection.

Does the GDPR provide indications to articulate an accountable approach to data?

Yes it does. Some relevant provisions of the GDPR can serve as an "accountable road map" to the processing of personal data:

- Recitals 39 and 83, Arts. 24(1) and 32, GDPR: Ensuring security measures are in place;
- Recital 78 and Art. 24(2), GDPR: Implementing data protection policies where appropriate;
- Recital 78 GDPR and Art. 25, GDPR: Adopting data protection by design and by default;
- Recital 81 and Art. 28, GDPR: Formalizing appropriate contracts with processors and sub-processors
- Recitals 42 and 82 and Arts. 7(1), 30, and 33(5), GDPR: Maintaining appropriate documentation of processing activities;
- Recitals 85–88 GDPR Arts. 33–34, GDPR: Recording and reporting data breaches;
- Recitals 84 and 89–95 GDPR and Arts. 35-36: Carrying out data protection impact assessments (DPIAs) where required by the type of processing in particular using new technologies, and taking into account the nature, scope, context and purposes of the processing;
- Recital 97 and Art. 37–39, GDPR: Assigning a data protection officer (DPO) where required;
- Recitals 98 and 100 and Art. 40–43, GDPR: Adopting codes of conduct and certification schemes where appropriate.

2.3 Useful terms

Anonymisation (anonymous information): means that personal data is rendered in such a way that the data subject is not or no longer identifiable (reference GDPR Recital 26). Compare also => *Pseudonymisation.*

Data breach (personal data): a breach of security leading to the accidental or unlawful destruction, loss, alteration, unauthorised disclosure of, or access to, personal data transmitted, stored or otherwise processed (GDPR Art. 4 n.12).

Data controller: 'the natural or legal person, public authority, agency or other body which, alone or jointly with others, determines the purposes and means of the processing of personal data; where the purposes and means of such processing are determined by Union or Member State law, the controller or the specific criteria for its nomination may be provided for by Union or Member State law (GDPR Art. 4 n.7).

Data processor: 'a natural or legal person, public authority, agency or other body which processes personal data on behalf of the controller (GDPR Art. 4 n.8).

Data protection impact assessment (DPIA): a process or tools to identify and minimise the risks that may arise from the processing of personal data as early as possible (GDPR Art. 35).

Data protection by design: controller's obligation to implement technical and organisational measures at the earliest stages of processing operations and to ensure that privacy and data protection are safeguarded from the start (GDPR Art. 25 (1)).

Data protection by default: controller's obligation to choose and implement default processing settings so that processing is strictly necessary to achieve the set and lawful purpose (GDPR Art. 25 (2)).

Data subject: an identified or identifiable natural person whom personal data refers to.

Informed consent: the consent given by the data subject and qualified as "freely given, specific, informed and unambiguous indication of the data subject's wishes by which he or she, by a statement or by a clear affirmative action, signifies agreement to the processing of personal data relating to him or her" (GDPR Art. 4 n.11).

Legal basis (for processing personal data): refers to the lawful and valid reason, foundation and framework upon which the controllers and processors establish and justify the processing of personal data. According

to the GDPR potential legal bases are: consent, contract, legal obligation, vital interests, public task, legitimate interests. (GDPR Art. 6).

Pseudonymisation: means the processing of personal data in such a manner that the personal data can no longer be attributed to a specific data subject without the use of additional information, provided that such additional information is kept separately and is subject to technical and organisational measures to ensure that the personal data are not attributed to an identified or identifiable natural person; (GDPR Art. 4 n.5).

Purpose(s) (of personal data processing): means the aim(s) of processing personal data (e.g. scientific research, preventing fraud, health). When the processing has multiple purposes, consent should be given for all of them (GDPR Recital 32).

Security measures: technical and organisational measures that the controller and the processor implement to ensure a level of security appropriate to the risk, state of the art, costs of implementation, nature, scope and purposes of processing. (see GDPR Art. 32).

3 Intellectual Property Rights and other non-personal data.

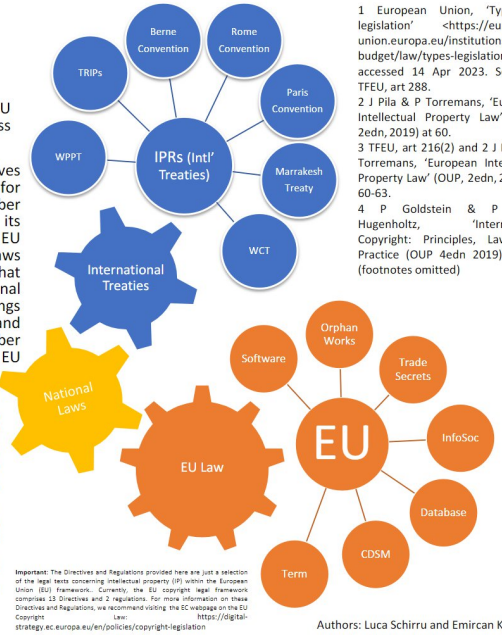
3.1 Fact Sheets

IPRs: *Relationship between Directives, National Laws and International Treaties*

Harmonization of IPRs: Harmonization is the process of aligning national laws with EU directives and international treaties to ensure consistency and coherence across different legal systems.

EU Law and the difference between EU Regulations and EU Directives: EU directives form the basis of intellectual property law in the EU. They provide a framework for national laws that govern the protection and enforcement of IPRs in each member state. While 'a "regulation" is a binding legislative act [and] must be applied in its entirety across the EU', 'a "directive" is a legislative act that sets out a goal that all EU countries must achieve [and] it is up to the individual countries to devise their own laws on how to reach these goals.' **1**. In practical terms, a relevant legal effect of it is that Regulations may "be invoked directly by individuals in proceedings before national courts – including vertical proceedings (against the state) and horizontal proceedings (against other individual.s) – as a source of individual rights and obligations" and "directives do not penetrate automatically and directly into the legal orders of Member States, and cannot be invoked before domestic courts in the manner of EU regulations".**2**

International Treaties: International treaties establish minimum standards for the protection and enforcement of IPRs, and are relevant to understand the functioning of IPRs in the EU. While it is clear from art 216(2) from the TFEU that [international] "agreements concluded by the Union are binding upon the institutions of the Union and on its Member States",**3** the legal effects of each IP-related International Treaty must be further and individually analyzed. On the International Treaties relevant to IPR, Goldstein and Hugenholtz (2019, 60) explain that "all countries of the E.U. belong to the Berne Union, adhere to the Rome Convention, and, through membership in the WTO, are bound by the TRIPs Agreement. The E.U. and its member states have also ratified the WIPO treaties. As a consequence, the harmonized rules on copyright and neighboring rights of the E.U. tend to require member states to offer more, but not less, protection than is required by the relevant international treaties".**4**



Important: The Directives and Regulations provided here are just a selection of the legal texts concerning intellectual property (IP) within the European Union (EU) framework. Currently, the EU copyright legal framework comprises 13 Directives and 2 regulations. For more information on these Directives and Regulations, we recommend visiting the EC webpage on the EU Copyright Law: https://digital-strategy.ec.europa.eu/en/policies/copyright-legislation

1 European Union, 'Types of legislation' <https://european-union.europa.eu/institutions-law-budget/law/types-legislation_en> accessed 14 Apr 2023. See also TFEU, art 288.
2 J Pila & P Torremans, 'European Intellectual Property Law' (OUP, 2edn, 2019) at 60.
3 TFEU, art 216(2) and 2 J Pila & P Torremans, 'European Intellectual Property Law' (OUP, 2edn, 2019) at 60-63.
4 P Goldstein & P Bernt Hugenholtz, 'International Copyright: Principles, Law, and Practice (OUP 4edn 2019), at 60 (footnotes omitted)

Authors: Luca Schirru and Emircan Karabuga

EU Legal Framework on Data
(main Directives, Regulations and Proposals)

General Data Protection Regulation (GDPR)
Regulation (EU) 2016/679: 'This Regulation lays down rules relating to the protection of natural persons with regard to the processing of personal data and rules relating to the free movement of personal data', and 'protects fundamental rights and freedoms of natural persons and in particular their right to the protection of personal data.' (GDPR, art. 1(1)(2))

Data Act (DA - proposal)
The proposed regulation aims to lay down: 'harmonised rules on making data generated by the use of a product or related service available to the user of that product or service, on the making data available by data holders to data recipients, and on the making data available by data holders to public sector bodies or Union institutions, agencies or bodies, where there is an exceptional need, for the performance of a task carried out in the public interest' (DA, art. 1(1))

Artificial Intelligence Act (AIA - proposal)
The proposed regulation aims to lay down: 'harmonised rules for the placing on the market, the putting into service and the use of artificial intelligence systems ('AI systems') in the Union; (a)prohibitions of certain artificial intelligence practices; (b)specific requirements for high-risk AI systems and obligations for operators of such systems; (c)harmonised transparency rules for AI systems intended to interact with natural persons, emotion recognition systems and biometric categorisation systems, and AI systems used to generate or manipulate image, audio or video content; (d)rules on market monitoring and surveillance.' (AIA, art. 1)

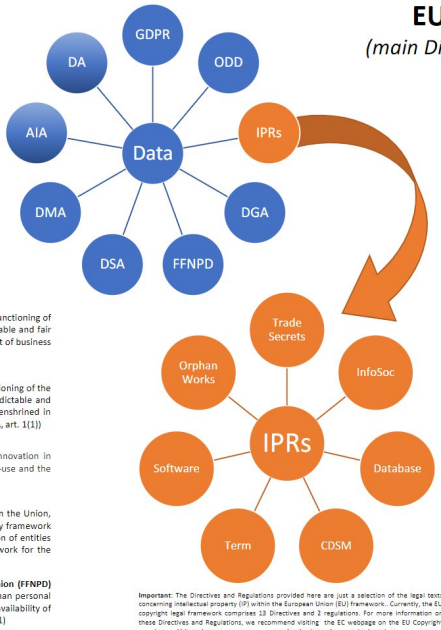
Digital Markets Act (DMA)
Regulation (EU) 2022/1925: 'The purpose of this Regulation is to contribute to the proper functioning of the internal market by laying down harmonised rules ensuring for all businesses, contestable and fair markets in the digital sector across the Union where gatekeepers are present, to the benefit of business users and end users.' (DMA, art. 1(1))

Digital Services Act (DSA)
Regulation (EU) 2022/2065: 'The aim of this Regulation is to contribute to the proper functioning of the internal market for intermediary services by setting out harmonised rules for a safe, predictable and trusted online environment that facilitates innovation and in which fundamental rights enshrined in the Charter, including the principle of consumer protection, are effectively protected.' (DSA, art. 1(1))

Open Data Directive (ODD)
Directive (EU) 2019/1024: 'In order to promote the use of open data and stimulate innovation in products and services, this Directive establishes a set of minimum rules governing the re-use and the practical arrangements for facilitating the re-use of' certain kinds of data. (ODD, art. 1(1))

Data Governance Act (DGA)
Regulation (EU) 2022/868: 'This Regulation lays down: (a) conditions for the re-use, within the Union, of certain categories of data held by public sector bodies; (b) a notification and supervisory framework for the provision of data intermediation services; (c) a framework for voluntary registration of entities which collect and process data made available for altruistic purposes; and (d) a framework for the establishment of a European Data Innovation Board." (DGA, art. 1(1))

Regulation on a framework for the free flow of non-personal data in the European Union (FFNPD)
Regulation (EU) 2018/1807: 'This Regulation aims to ensure the free flow of data other than personal data within the Union by laying down rules relating to data localisation requirements, the availability of data to competent authorities and the porting of data for professional users.' (FNNPD, art. 1)



Important: The Directives and Regulations provided here are just a selection of the legal texts concerning intellectual property (IP) within the European Union (EU) framework. Currently, the EU copyright legal framework comprises 13 Directives and 2 regulations. For more information on these Directives and Regulations, we recommend visiting the EC webpage on the EU Copyright Law: https://digital-strategy.ec.europa.eu/en/policies/copyright-legislation

Trade Secrets Directive
Directive (EU) 2016/943: 'This Directive lays down rules on the protection against the unlawful acquisition, use and disclosure of trade secrets.' (art.1(1))

CDSM Directive
Directive (EU) 2019/790: 'This Directive lays down rules which aim to harmonise further Union law applicable to copyright and related rights in the framework of the internal market, taking into account, in particular, digital and cross-border uses of protected content. It also lays down rules on exceptions and limitations to copyright and related rights, on the facilitation of licences, as well as rules which aim to ensure a well-functioning marketplace for the exploitation of works and other subject matter.' (art.1(1))

Term Directive
Directive 2006/116/EC on the term of protection of copyright and certain related rights.

InfoSoc Directive
Directive 2001/29/EC: 'This Directive concerns the legal protection of copyright and related rights in the framework of the internal market, with particular emphasis on the Information society.' (art. 1(1)).

Directive on the legal protection of databases
Directive 96/9/EC: 'This Directive concerns the legal protection of databases in any form.' (art.1(1))

Directive on Orphan Works
Directive 2012/28/EU: 'This Directive concerns certain uses made of orphan works by publicly accessible libraries, educational establishments and museums, asbroadcasting well as by archives, film or audio heritage institutions and public-service organisations, established in the Member States, in order to achieve aims related to their public-interest missions.' (art. 1 (1))

Directive on the legal protection of computer programs
Directive 2009/24/EC: 'in accordance with the provisions of this Directive, Member States shall protect computer programs, by copyright, as literary works within the meaning of the Berne Convention for the Protection of Literary and Artistic Works.' (art. 1 (1))

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3.2 FAQ

3.2.1 Intellectual Property (general)

Can I use third-party material (images, text, data, video, etc.) in my works (training materials, books, articles, etc.)?

It depends. In addition to data that may be protected under the GDPR or regulated under other Directives/Regulations/Laws (e.g. 'research data' under the Open Data Directive and Internet of Things (IoT) data under the Data Act), some materials like photographies, videos, text, databases and information deemed as secrets can be protected by Intellectual Property Rights (IPRs), which substantially limit the authorized uses without previous and express authorization of the rightsholder.

What is encompassed under the Intellectual Property Rights "umbrella"?

According to the World Intellectual Property Organization (WIPO, 2020, 3),

> IP is often divided into two main categories: Industrial property includes patents for inventions, industrial designs, trademarks and geographical indications. Copyright and related rights cover literary, artistic and scientific works, including performances and broadcasts.

A brief description of the scope of protection of these different IP rights is below:

IPR	*Description*
Patents	"**An invention can be defined as a product or process that offers a new way of doing something, or a new technical solution to a problem**. To qualify for patent protection, an invention must be of some **practical use** and must offer something **new** which is not part of the existing body of knowledge in the relevant technical field (what lawyers call the prior art). But these requirements of *utility* and *novelty* are not enough; the invention must also involve an ***inventive step*** – something non-obvious that could not just have been deduced by someone with average knowledge of the technical field. Furthermore, the invention must **not fall under *non-patentable subject***

	matter." (WIPO, 2020, 5) (emphasis added)
Trademarks	"A trademark is a **sign capable of distinguishing** the goods or services of one enterprise from those of other enterprises.[...] All sorts of signs may be used as trademarks – words, letters, numbers, symbols, colors, pictures, three-dimensional signs such as shapes and packaging, holograms, sounds, even tastes and smells. To be eligible for registration, the basic principle is that a trademark must be **distinctive**, so it cannot just be a generic description of the product or service. Nor can it be identical (or very similar) to a trademark already registered or used for that type of product or service." (WIPO, 2020, 12-13) (emphasis added)
Industrial Designs	"Industrial design rights cover those elements of a product that are **aesthetic or ornamental** – the way it looks and feels. [...] Industrial designs are applied to a wide variety of industrial products and handmade goods: cars, telephones, computers, packaging and containers, technical and medical instruments, watches, jewelry, electrical appliances, textile designs, and many other types of goods." (WIPO, 2020, 8) (emphasis added)
Geographical Indications	"A geographical indication is a **sign used on products that have a specific geographical origin** and possess qualities or a reputation that are due to that origin. [...]There are different laws protecting geographical indications and different systems of recognition in different countries, so international law is developing ways to strengthen protection across national boundaries. " (WIPO, 2020, 16) (emphasis added)
Copyright and related rights	"Copyright, or authors' right, is a legal term used to describe the rights that creators have in their **literary, artistic and scientific works.** Copyright covers an enormous range of works – not just books, music, paintings, sculpture and films, but also computer programs, databases, advertisements, maps and technical drawings, among other things. There are also rights related to the copyright of the creators that protect the

	interests of those closely associated with copyrighted works, including performers, broadcasters and producers of sound recordings." (WIPO, 2020, 20) (emphasis added)

Source: designed with information extracted from WIPO (2020).

Upon building of training and educational material, as well as leading training sessions, which IPR(s) should be considered?

Considering that training and educational material often reuses excerpts of articles and books, images and/or audiovisual material which may be protected – just like the output material itself - under copyright and related rights, these are usually the focus of the discussion. However, caution is also advised when using trademarks, commercial signs and information that could be deemed secret. Finally, releasing technical information on patentable inventions may eventually impede its owner's ability to apply for patent protection, due to the lack of novelty.

3.2.2 Copyright

How does the legal framework on copyright operate in the EU?

EU directives form the basis of intellectual property law and, therefore, copyright in the EU. They provide a framework for national laws that govern the protection and enforcement of IPRs in each Member State. While '*a "regulation" is a binding legislative act [and] must be applied in its entirety across the EU*', '*a "directive" is a legislative act that sets out a goal that all EU countries must achieve [and] it is up to the individual countries to devise their own laws on how to reach these goals*'.[15] Copyright is nationally regulated and national law must be considered, despite the EU legal harmonisation, which is the process of aligning national laws with EU directives and international treaties to ensure consistency and coherence across different legal systems.

[15] European Union, 'Types of legislation' https://european-union.europa.eu/institutions-law-budget/law/types-legislation_en accessed 14 Apr 2023. See also TFEU, art 288.

Which are the main copyright-related directives in the EU?

Several Directives and Regulations form part of what is known as "EU Copyright Law":[16]

i. Directive 93/83/EEC on the coordination of certain rules concerning copyright and rights related to copyright applicable to satellite broadcasting and cable retransmission;
ii. Directive 96/9/EC on the legal protection of databases;
iii. Directive 2001/84/EC on the resale right for the benefit of the author of an original work of art;
iv. Directive 2001/29/EC on the harmonisation of certain aspects of copyright and related rights in the information society;
v. Directive 2004/48/EC on the enforcement of intellectual property rights;
vi. Directive 2006/115/EC on rental right and lending right and on certain rights related to copyright in the field of intellectual property;
vii. Directive 2006/116/EC on the term of protection of copyright and certain related rights;
viii. Directive 2009/24/EC on the legal protection of computer programs;
ix. Directive 2011/77/EU on the term of protection of copyright and certain related rights amending the previous Term Directive;
x. Directive 2012/28/EU on certain permitted uses of orphan works;
xi. Directive 2014/26/EU on collective management of copyright and related rights and multi-territorial licensing of rights in musical works for online use in the internal market;
xii. Directive 2017/1564/EU on certain permitted uses of certain works and other subject matter protected by copyright and related rights for the benefit of persons who are blind, visually impaired or otherwise print-disabled;
xiii. Regulation 2017/1563/EU on the cross-border exchange between the Union and third countries of accessible format copies of certain works and other subject matter protected by copyright and related rights for the benefit of persons who are blind, visually impaired or otherwise print-disabled;
xiv. Regulation 2017/1128/EU on cross-border portability of online content services in the internal market;
xv. Directive 2019/789/EU on the exercise of copyright and related rights applicable to certain online transmissions of broadcasting organisations and retransmissions of television and radio programme;
xvi. Directive 2019/790/EU on copyright and related rights in the Digital Single Market;

[16] European Commission, 'The EU copyright legislation' https://digital-strategy.ec.europa.eu/en/policies/copyright-legislation

xvii. Directive 2019/1024/EU on open data and the re-use of public sector information.

However, it should be remembered that **copyright is a matter to be addressed by national law**, and the directives are just a part of the legal framework on copyright that should be considered in the EU. More information on the functioning of the Copyright Legal Framework in the EU can be found in the Fact Sheet '*IPRs: Relationship between Directives, National Laws and International Treaties*'.

What is needed for a work to be protected under copyright in the EU?

The protection of works under EU copyright law requires the satisfaction of criteria concerning originality and expression. EU copyright law has relied on case law to refine and clarify the scope of protection. In the EU, a work must be **original** in order to qualify for copyright protection. The notion of originality is harmonized in the EU through the case law of the CJEU.[17] Following the landmark decision of the CJEU in *Infopaq*[18] and its subsequent case law,[19] a work is considered "original" if it resembles the "author's own intellectual creation".[20] Hence, "originality" can be said to arise from the unique elements embodied in a work that resembles the author's personality or personal touch.[21] Similarly, in the *Football Dataco* case, the CJEU affirmed that copyright protection for databases only applies if they are original in the selection or arrangement of their contents.[22]

Echoed by Directive 2009/24/EC and Directive 96/9/EC, Article 2 of the WIPO Copyright Treaty excludes certain types of works from copyright protection, including ideas, procedures, methods of operation, and mathematical concepts. This exclusion acknowledges the **idea/expression dichotomy** and ensures that copyright law does not impede creativity or innovation in

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17 Tatiana-Eleni Synodinou, Philippe Jougleux, Christiana Markou and Thalia Prastitou-Merdi, 'EU Internet Law in the Digital Single Market' (Springer Cham 2021), 183.

18 Case C 5/08 Infopaq International A/S v Danske Dagblades Forening [2009] ECLI:EU:C:2009:465.

19 Case C-393/09 Bezpečnostní softwarová asociace – Svaz softwarové ochrany v Ministerstvo kultury [2011] ECLI:EU:C:2010:816, para 45; Case C-145/10 Eva-Maria Painer v Standard Verlags GmbH [2012] ECLI:EU:C:2013:138, para 87.

20 Tatiana-Eleni Synodinou, Philippe Jougleux, Christiana Markou and Thalia Prastitou-Merdi, 'EU Internet Law in the Digital Single Market' (Springer Cham 2021), 183.

21 ibid.

22 Case C-604/10 Football Dataco Ltd v Yahoo! UK Ltd & Others [2012] ECR I-619.

these respects. Under the idea/expression dichotomy, copyright protection only applies to the specific expression of an idea, rather than the underlying idea itself. This implies that an author is not entitled to exclusive rights over an idea or concept, but solely over its manifestation in tangible form.

Under copyright, what exclusive rights are envisaged in the EU legal framework?

Just as an example, the InfoSoc Directive[23] regulates the Reproduction right (art 2), the right of Communication to the Public (art 3), the right of Making Available (art 3), and the Distribution right (art 4). One issue that is highlighted in the literature[24], is the wide scope of the Reproduction Right as it can be seen in Art. 2 of the InfoSoc, as it would encompass 'the exclusive right to authorise or prohibit direct or indirect, temporary or permanent reproduction by any means and in any form, in whole or in part'. On a related note, the Copyright Directive provides that retransmission of programmes 'must be authorised by the holders of the exclusive right of communication to the public.' Other legal texts, as the Berne Convention for the Protection of Literary and Artistic Works also specifically address the right of Adaptation (art 12), the right of Translation (art 8), among others.

Does this mean that I need to ask for authorisation for using any third-party copyrighted material?

Not necessarily. Apart from the uses authorized under a license, it is also possible to use copyrighted works that are in the (i) public domain or (ii) that the use is comprised under the Limitations and Exceptions (L&Es). Also, remember that the material that you are intending to use may not be covered by copyright OR that it may be covered by other exclusive rights, as is the case of databases (see below) which may require additional, and different, authorizations.

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23 Directive 2001/29/EC of the European Parliament and of the Council of 22 May 2001 on the harmonisation of certain aspects of copyright and related rights in the information society [2001] OJ L167.

24 T Margoni & M Kretschmer, A Deeper Look into the EU Text and Data Mining Exceptions: Harmonisation, Data Ownership, and the Future of Technology (2022) 71(8) GRUR International 689.

What is the Sui Generis Database Right?

The Sui Generis Database Right (SGDR) (see also Section 3.2.3) refers to the prerogative of the maker of a database to prevent acts of extraction or reutilization of substantial parts of the content when a substantial investment was made in the obtaining, verification or presentation of the database. Notably, this right does not apply to databases created by means of sensors or other physical components of connected products and other machine-generated data which are governed by the Data Act.[25]

In practice, what are the effects of a work being in public domain?

According to one definition, information being "in the public domain" means information "whose use, absent special reasons to think otherwise, is permissible to anyone."[26] In practice, 'being in the public domain' often means that the exclusive economic rights on that copyrighted work have expired and, therefore, everyone can use that work, even for commercial purposes (although the moral rights of the author, e.g. attribution of authorship, should continue to be respected). In other cases, a work can be expressly placed in the public domain by its author, such as when using the CC0 (CC Zero) license.[27]

What is the difference between moral rights and economic rights?

Economic rights are connected to the economic value that can be derived from the work. They allow the authors to monetize their creations, by means of control their reproduction, distribution and other forms of exploitation. On the other hand, moral rights reflect the connection that authors (along with their reputation) have with their work. As personal rights of authorship, they are 'concerned with the attribution and integrity of works, and generally involve only indirect commercial consequences.'[28]

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25 See Article 43 and Recital 112 of the Data Act.

26 Benkler, Yochai, Free as the Air to Common Use: First Amendment Constraints on Enclosure of the Public Domain. Available at SSRN: https://ssrn.com/abstract=168609 or http://dx.doi.org/10.2139/ssrn.168609. For a discussion on the possible definitions of public domain, see James Boyle, The Second Enclosure Movement and the Construction of the Public Domain. Available at SSRN: https://ssrn.com/abstract=470983 or http://dx.doi.org/10.2139/ssrn.470983.

27 https://creativecommons.org/share-your-work/cclicenses/

28 Mira T Sundara Rajan, Moral rights: the future of copyright law?, Journal of Intellectual

Is it enough to check the InfoSoc, the CDSM or any specific directive to confirm whether a use falls under Limitations and Exceptions (L&E)?

While the InfoSoc Directive and the CDSM Directive provide a legal framework for lawful exceptions or limitations to copyright in EU copyright law (such as use for illustration in teaching, or scientific research purposes), determining whether a particular use is covered by L&E requires more than a mere reference to these directives. Specific conditions and limitations for each L&E are established in the national copyright laws of each EU Member State. The determination may also be influenced by other international treaties, directives or agreements that are relevant to the particular work or use in question. As such, the applicability of L&E must be determined on a case-by-case basis.

If it is not in public domain and the use is not covered by L&E, does it mean that I am not allowed to use it?

If the work (i) is protected under copyrights, (ii) is not in the public domain, (iii) the use is not covered by L&Es and (iv) was not licensed by the rightsholder, then there is a high risk of copyright infringement.

What is the difference between Free Software and Open-source Software?

With the original idea dating back to Richard Stallman's Free Software Movement of the early 1980s, who sought to preserve the early collaborative ideals of the computer revolution, the label *free* was created as an association with *free speech* – embodying the freedoms to run the program, to study and change it (in source code form), to redistribute both its copies and modified versions, while disallowing any commercial modifications.[29] To avoid linguistic confusion, the term 'open source' was coined, its arrival coinciding with some controversies relating to the watering down of the original philosophy (products which were technically open-source while still finding ways to limit the freedoms of the user – a

Property Law & Practice, Volume 14, Issue 4, April 2019, Pages 257–258, https://doi-org.kuleuven.e-bronnen.be/10.1093/jiplp/jpz008

[29] Stallman R (1985) The GNU Manifesto. Available GNU Operating System, https://www.gnu.org/gnu/manifesto.html.

practice labelled *tivoization* in memory of an open-source device imposing severe limits on its users).[30]

Today, the two philosophies exist in parallel - the definition of open-source coined by the Open Source Initiative (OSI) focusing on the practical aspects (free redistribution, provision of source code, right to modification, no discrimination etc.) while the Free Software initiative retains its human freedoms-based approach.

Orphan works: what happens if the author/owner is unknown?

Orphan works (or phonograms) are those which "none of the rightholders in that work or phonogram is identified or, even if one or more of them is identified, none is located despite a ***diligent search*** for the rightholders having been carried out and recorded" (Orphan Works Directive, Art. 2(1)).

If a diligent search produced no results, there is a possibility of the work being an 'orphan work'. In the EU, the permitted uses of orphan works are regulated under national laws, as they pertain to the copyright field. In the regional level, the Directive 2012/28/EU ('Orphan Works Directive') addresses these works. The rules provided in the directive refer to a specific set of institutions, i.e., "publicly accessible libraries, educational establishments and museums, as well as by archives, film or audio heritage institutions and public-service broadcasting organisations, established in the Member States" and such uses shall be carried out "in order to achieve aims related to their public-interest missions" (Orphan Works Directive, Art. 1(1)).

What should an investigation entail to be considered as a diligent search?

A diligent search is an essential step to legitimize the use of a work as an 'orphan work' and must "be carried out prior to the use of the work or phonogram." (Orphan Works Directive, Art. 3(1)). The diligent search, according to Art. 3(1) of Orphan Works Directive, shall consider "the appropriate sources for the category of works and other protected subject-matter in question". The exact sources where such search should be carried

[30] Drazewski K (2024) Copyright as a Constraint on Creating Technological Value, Springer Cham https://doi.org/10.1007/978-3-031-51276-6, SpringerLink, p. 92.

out shall be determined by the national law (Orphan Works Directive, Art. 3(2)), in addition to those listed in the Annex of the Orphan Works Directive.

Important: further information on the uses of Orphan Works/Phonograms may be found in the applicable national laws, the Directive 2012/28 and further applicable regulation.

If it is not copyrighted work, does it mean that I can use the work / data?

Not necessarily. As mentioned before, copyright is not the only exclusive right that may require further steps and caution before using third-parties' content. Other exclusive rights may arise, for example, sui generis database rights (item 3.2.3.) and specific rules applicable to trade secrets (item 3.2.4.)

3.2.2.1 Copyright and Open Science

What is Open Science?

As defined in the UNESCO Recommendation, Open Science is "an inclusive construct that combines various movements and practices aiming to make multilingual scientific knowledge openly available, accessible and reusable for everyone, to increase scientific collaborations and sharing of information for the benefits of science and society, and to open the processes of scientific knowledge creation, evaluation and communication to societal actors beyond the traditional scientific community".[31]

Mendez and others (2020, 22) propose that Open Science is not an end in itself, but a means to a larger effort, where "Open Science must ultimately be embedded as part of a larger more systemic effort to foster all practices and processes that enable the creation, contribution, discovery and reuse of research knowledge more reliably, effectively and equitably". Open knowledge should ideally encompass all human endeavors, not just scientific research, but also arts and humanities, engineering, medicine, and all areas of professional knowledge.

The broad scope of what is encompassed by 'Open Science' is well depicted by the taxonomy found in the FOSTER Portal, listing "Open Access", "Open

[31] UNESCO Recommendation on Open Science (2021) <https://en.unesco.org/science-sustainable-future/open-science/recommendation>

Data", "Open Research", "Open Science Evaluation", "Open Science Policies" and "Open Science Tools" as elements of OS.[32]

Beside open licensing, which are some of the most common copyright-related issues on Open Science?

One important aspect of Open Science is Open Access. According to the definition provided by UNESCO:

> Open access (OA) means free access to information and unrestricted use of electronic resources for everyone. Any kind of digital content can be OA, from texts and data to software, audio, video, and multi-media. While most of these are related to text only, a growing number are integrating text with images, data, and executable code. OA can also apply to non-scholarly content, like music, movies, and novels. A publication is considered in Open access if:
>
> - its content is universally and freely accessible, at no cost to the reader, via the Internet or otherwise;
> - the author or copyright owner irrevocably grants to all users, for an unlimited period, the right to use, copy, or distribute the article, on condition that proper attribution is given;
> - it is deposited, immediately, in full and in a suitable electronic form, in at least one widely and internationally recognized open access repository committed to open access.[33]

Open Access, today, cannot be analysed without considering the whole commercial scientific publishing sector dynamics. One example is the current business model that combines OA publishing with substantial Article Processing Charge (APC),[34] that can ultimately promote inequality if not properly addressed.[35]

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32 Foster Open Science Website (n.d.) https://www.fosteropenscience.eu/resources.

33 UNESCO, 'What is Open Access?' (n.d.) https://en.unesco.org/open-access/what-open-access

34 "Article processing charges (or APCs) are fees to be paid by the author (author fees) to publish his/her research article in immediate OA (Gold OA). The cost of an APC varies greatly depending on the publisher: it can be determined cost-effectively (non-profit OA) or it can include a profit margin (for-profit OA). Keep in mind that there are also OA journals that do not charge APCs, allowing you to make your article available in OA without having to pay for it.". KU Leuven, 'Glossary' (What is Open Science, n.d.) accessed 12 Apr 2023 https://www.kuleuven.be/open-science/what-is-open-science/scholarly-publishing-and-open-access/glossary#APC

35 European Commission, Directorate-General for Research and Innovation, Mendez, E., Lawrence, R., Progress on open science: towards a shared research knowledge system: final

Regarding the business models in scientific publishing, what are Green, Bronze, Gold, Hybrid and Diamond OA?

Type of OA	*Description*
Bronze OA	"In the Bronze OA model the journal is officially subscription-only and no author fee is charged for OA publishing. However, the publisher can choose, for a brief period, to release a publication free to read on their website but without an open license like Creative Commons (perhaps for marketing purposes or in response to health emergencies such as the COVID-19 pandemic). Bronze OA is therefore not truly OA since the publisher can close off free access at any time, whereas genuinely OA publications have an open license that ensures the publication to be permanently and freely accessible with clear agreements about sharing and reuse."
Green OA	"Green OA, also known as self-archiving or open archiving, means that you archive a digital copy (usually the accepted version) of your publication in an online repository. This archival copy is made available to the public – often after an embargo period."
Gold OA	"Gold OA, a.k.a. open publishing, means that the publisher makes the published version of your work immediately and freely available to the public. The cost of publishing is either carried by the author (who pays an author fee) or by a third party (Diamond OA), but never by the reader.[...] There are different types of Gold OA, such as Full OA and Hybrid OA."
Full OA	"In a Full OA journal, opposed to a Hybrid OA journal, all the articles are published in immediate OA, without embargo."
Hybrid OA	"A Hybrid OA journal, opposed to a Full OA journal, is a subscription-based journal that offers authors the option to publish their individual article in OA by payment of an author

report of the open science policy platform, Brussels: Publications Office 2020, https://op.europa.eu/s/zQxP p 18; ALLEA Statement on Open Access Publication Under "Big Deals" and the New Copyright Rules. 2022

	fee. The articles that are published in OA are freely available to the readers, but the journal as such is still published behind a paywall."
Diamond OA	"Diamond OA is a Gold Open Access publication system in which there is neither cost to the reader (no subscription cost) nor to the author(s) (no author fees). This is made possible because the publishing infrastructure is subsidized by a third party (e.g. a funding agency or a consortium of university libraries). Diamond OA is often (but not always) determined by a non-profit mission. Therefore, the KU Leuven Fund for Fair OA sponsors various Diamond OA initiatives."

Designed with information extracted from KU Leuven, 'Glossary' (What is Open Science, n.d.) accessed 2 Aug 2024 https://www.kuleuven.be/open-science/what-is-open-science/scholarly-publishing-and-open-access/glossary

What is "double-dipping"?

Double-dipping is a term usually employed while addressing the Hybrid OA:

> This model is called "double dipping" as the journal makes a double profit: on the one hand, the author pays a fee to get his/her article published in OA, and on the other hand, the library/reader pays a subscription fee to have access to the other articles in that same journal.36

What are Secondary Publication Rights (SPRs)?

A Secondary Publication Right (SPR) can be understood as "a right for the author of a scientific publication to make it available online for free following a given embargo period".[37] Legislative measures concerning SPRs are being introduced in countries like Austria, Germany, The Netherlands, and Belgium. In Belgium, for example, even if the author has assigned his rights to a publisher, they can make the manuscript freely available in twelve months (for humanities and social sciences) or six months (for other

[36] KU Leuven, 'Glossary' (What is Open Science, n.d.) accessed 2 Aug 2024 <https://www.kuleuven.be/open-science/what-is-open-science/scholarly-publishing-and-open-access/glossary>

[37] Angelopoulos, 2022, 4.

sciences) after the first publication, in case the article was a product of a public-funded research (Belgium Code of Economic Law, Art. XI. 196 2 §).

Are SPRs present in all EU countries?

No. The fact that SPRs are still largely nationally driven is an aspect that from the point of view of a European research space is seen as harmful legal fragmentation. Nevertheless, the interest in having this kind of publication openly accessible is not simply a national priority but is part a broader vision for a European research space as exemplified by the Commission Recommendation 2018/790 on access to and preservation of scientific information.[38]

What are Rights Retention Strategies?

On the organizational level, and in order to promote Open Access, initiatives like those under the cOAlition S are proposing Rights Retention Strategies (RRS),[39] which requires changes in different nodes of the dynamics between funding organizations, researchers and publishers, and that can be summarized in the text below, part of the Plan S guidance:

> Where possible, cOAlition S members will ensure by way of funding contracts or agreements that the authors or their institutions retain copyright as well as the rights that are necessary to make a version (either the VoR, the AAM or both) immediately available under an open license. To this end, cOAlition S will develop or adopt a model 'License to Publish' for their grantees. (cOAlition S, n.d., 2)

The recent Self-Archiving Policy[40] implemented by the University of Cambridge and the Plan S Rights Retention Strategy[41] are examples of these measures.

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38 Commission Recommendation 2018/790 on access to and preservation of scientific information [2018] OJ L 134/12

39 Coalition S (n.d.) Accelerating the transition to full and immediate Open Access to scientific publications <https://www.coalition-s.org/wp-content/uploads/PlanS_Principles_and_Implementation_310519.pdf>

40 https://unlockingresearch-blog.lib.cam.ac.uk/?p=3521&s=08

41 https://www.coalition-s.org/rights-retention-strategy/

3.2.2.2 Licensing

What is a license?

A license is a legal instrument representing the terms under which the author of a work consents for this work to be used by other parties. A license can e.g. specify that a purchased copy of a work can be used in household conditions but any commercial use is prohibited without express permission of the rights holder.

What is Open Data?

According to the Open Data Directive (ODD), Open Data as a concept is generally understood to denote data in an open format that can be freely used, re-used and shared by anyone for any purpose (Recital 16 ODD).

What are Open Databases?

Databases using an open license, such as the Open Database License (ODbl) allow users to freely share (copy, distribute, use) the database, to create works on its basis, as well as to modify, transform and build upon the database.

What are open licenses?

An open license can be defined as "one which grants permission to access, re-use and redistribute a work with few or no restrictions"[42] depending on the chosen license.

For the purposes of this training material, we shall use the "Creative Commons" open licenses as the main examples of this kind of licenses. And this is not because they are the only existing open licenses, but they are the most adopted licensing framework, largely used in EC-related documents as part of the Commission Decision of 12 December 2011 on the reuse of Commission documents (2011/833/EU).[43]

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[42] Open Knowledge Foundation, 'Open Definition: Defining Open in Open Data, Open Content and Open Knowledge' (n.d.) https://opendefinition.org/guide/

[43] Other examples could include Open Data and Open Databases - open licenses recommended and commonly used for datasets and databases.

What are Creative Commons Licenses?

Contrary to the default rule of "All Rights Reserved" under copyright law, which requires permission for (almost) every use of a work, Creative Commons (CC) aims to create an environment in which "Some Rights Reserved" or even "No Rights Reserved" become standard.[44] CC provides six standard-form licenses (see graphic below), which allow creators of literary, musical, and audiovisual works to authorize wide dissemination and transformative use of their works without relinquishing their copyrights.[45] This means that when authors grant open licenses to the public on a royalty-free basis, their works are still copyright-protected.[46] Instead, they have opted not to exercise certain exclusive rights, such as the right to prevent others from using their work, the right to control its use, and the right to monetize their work.[47] However, CC has also developed the CC0 dedication, which enables authors to renounce all their rights to their work with respect to copyright and related matters.[48]

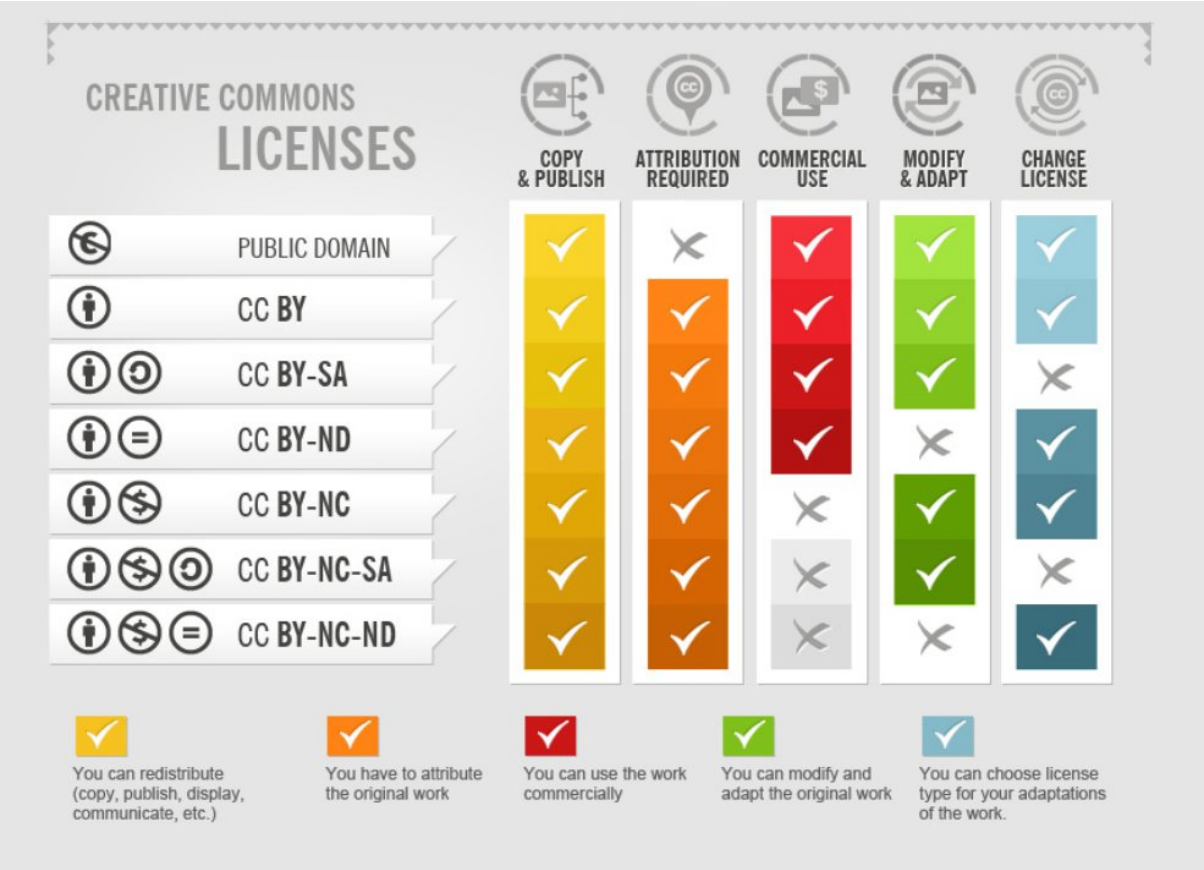
44 Lucie Guibault, 'Open Content Licensing: From Theory to Practice – An Introduction." In Open Content Licensing: From Theory to Practice, edited by Lucie Guibault and Christina Angelopoulos (Amsterdam University Press 2011) 7, 8.

45 İbid.

46 Till Kreutzer, 'User-Related Assets and Drawbacks of Open Content Licensing' In Open Content Licensing: From Theory to Practice, edited by Lucie Guibault and Christina Angelopoulos (Amsterdam University Press 2011) 107, 112.

47 ibid.

48 Marie-Christine Janssens, Arina Gorbatyuk, Sonsoles Pajares Rivas, 'Copyright Issues on the use of images on the Internet' In Research Handbook on Intellectual Property and Cultural Heritage (Edward Elgar 2022) 191, 204.



Source :https://foter.com/blog/how-to-attribute-creative-commons-photos/. License: CC BY-SA 3.0

Are CC licenses the only 'open' licenses?

No. There are multiple 'open' licenses, some of the specific to a particular set of works, as is the case of the FLOSS (Free, Libre and Open Source Software) licenses. Just among these particular category of licenses, there are multiple types of license, as it can be seen from the list made available by the GNU Operating System – Free Software Foundation.[49]

Is being licensed under a CC license the same as being in public domain?

No; according to the Creative Commons:

[49] GNU Operation System, 'Various Licenses and Comments about Them' (06 Apr 2023) https://www.gnu.org/licenses/license-list.html

> CC licenses are copyright licenses, and depend on the existence of copyright to work. CC licenses are legal tools that creators and other rights holders can use to offer certain usage rights to the public, while reserving other rights. Those who want to make their work available to the public for limited kinds of uses while preserving their copyright may want to consider using CC licenses. Others who want to reserve all of their rights under copyright law should not use CC licenses.[50]

What if the national law goes against the terms of the CC license?

The CC licenses were built to work in the international level as much as possible. However, there are times that their terms may conflict with the national copyright law. And this may happen in cases where the Limitations and Exceptions of a copyright law authorize some use that would be allowed under a copyright license. The current CC-BY License 4.0 addresses this issue in Sec 2(a)(2):

> Section 2(a)(2): Exceptions and Limitations. For the avoidance of doubt, where Exceptions and Limitations apply to Your use, this Public License does not apply, and You do not need to comply with its terms and conditions.

Do CC licenses cover other IP rights or personality rights?

No. Generally, CC licenses are meant to deal with copyrights and, in the case of the version 4.0, sui generis database rights (SGDR). As stated by the Creative Commons, '[t]he license may not give you all of the permissions necessary for your intended use. For example, other rights such as publicity, privacy, or moral rights may limit how you use the material.'[51] Also, section 2(b)(1)(2) of the CC-BY 4.0 provides that:

> Moral rights, such as the right of integrity, are not licensed under this Public License, nor are publicity, privacy, and/or other similar personality rights; however, to the extent possible, the Licensor waives and/or agrees not to assert any such rights held by the Licensor to the limited extent necessary to allow You to exercise the Licensed Rights, but not otherwise.

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50 Creative Commons, 'Frequently Asked Questions' (13 Jan 2023) https://creativecommons.org/faq/#is-creative-commons-against-copyright

51 Creative Commons, 'Attribution 4.0 International (CC BY 4.0)' https://creativecommons.org/licenses/by/4.0/

Patent and trademark rights are not licensed under this Public License.

Besides the licensing frameworks addressed in this Section, are there other copyright-related tools that may be employed to promote Open Science?

Important measures are being adopted both in the legislative and organizational levels, for example: (i) Rights Retention Strategies (administrative/organizational level) and (ii) Secondary Publication Rights (legislative level).[52]

3.2.3 Sui Generis Database Rights (SGDR)

What are the *sui generis* database rights?

Despite being addressed in the same Directive as the copyright protection to databases, these rights are different in their scope and justification and apply irrespectively of whether or not the database is eligible for protection under copyright or by other rights.

The sole criterion for the database to be protected under the SGDR is to demonstrate that "there has been qualitatively and/or quantitatively a substantial investment in either the obtaining, verification or presentation of the contents to prevent extraction and/or re-utilization of the whole or of a substantial part [...] of the contents of that database" (art 7(1) of the Database Directive).

What do "extraction" and "re-utilization" mean?

According to Art. 7 (2)(a)(b) of the Database Directive, these terms shall have the following meanings:

> (a) 'extraction' shall mean the permanent or temporary transfer of all or a substantial part of the contents of a database to another medium by any means or in any form;

[52] See, eg, European Commission, Directorate-General for Research and Innovation, Angelopoulos, C., Study on EU copyright and related rights and access to and reuse of scientific publications, including open access : exceptions and limitations, rights retention strategies and the secondary publication right, Publications Office of the European Union, 2022, **https://data.europa.eu/doi/10.2777/891665**.

> (b) 're-utilization' shall mean any form of making available to the public all or a substantial part of the contents of a database by the distribution of copies, by renting, by on-line or other forms of transmission. The first sale of a copy of a database within the Community by the rightholder or with his consent shall exhaust the right to control resale of that copy within the Community.

If one of the legal requirements is "substantial investment", what is usually considered as such?

This matter must be assessed on a case-by-case basis. The Database Directive's Recitals and EU case law may provide some guidance.

By "investment", Recital 40 of the Database Directive, provides that it may "consist in the deployment of financial resources and/or the expending of time, effort and energy". As an example of what can or cannot be considered as "substantial investment", Recital 19 of the Database Directive provides that "as a rule, the compilation of several recordings of musical performances on a CD [...] does not represent a substantial enough investment to be eligible under the sui generis right".

Cases like the *Fixtures Marketing*[53] and the *British Horseracing Board*[54] give us some additional information. In the *British Horseracing Board*, it is clear that the aforementioned investment should not address the *creation* of the material but its *collection*:

> [...] the expression 'investment in ... the obtaining ... of the contents' of a database must, [...] be understood to refer to the resources used to seek out existing independent materials and collect them in the database, and not to the resources used for the creation as such of independent materials.[55]

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53 Case C-338/02 Fixtures Marketing Ltd v Svenska Spel AB [2004] ECR I-10497

54 Case C-203/02 The British Horseracing Board Ltd and Others v William Hill Organization Ltd [2004] ECR I-10415

55 Case C-203/02 The British Horseracing Board Ltd and Others v William Hill Organization Ltd [2004] ECR I-10415, para 31.

The contributions brought by the *Fixtures Marketing* case are twofold. The first one concerns the "qualitative" and "quantitative" terms: "[t]he quantitative assessment refers to quantifiable resources and the qualitative assessment to efforts which cannot be quantified, such as intellectual effort or energy [...]"[56]. The second one concerns the analysis, in that case of the investments in the verification and presentation of contents:

The expression 'investment in … the … **verification** … of the contents' of a database must be understood to refer to the resources used, with a view to ensuring the reliability of the information contained in that database, to monitor the accuracy of the materials collected when the database was created and during its operation. The expression 'investment in … the … **presentation** of the contents' of the database concerns, for its part, the resources used for the purpose of giving the database its function of processing information, that is to say those used for the systematic or methodical arrangement of the materials contained in that database and the organisation of their individual accessibility[57].[emphasis added]

How is the copyright protection to databases different from the *sui generis* database rights?

There are multiple differences between both rights, including but not limited to the (i) requirements for protection, (ii) exceptions to the exclusive rights, and (iii) term of protection.

Requirements:

- **Copyright protection:** copyright protection shall be granted to databases when "by reason of the selection or arrangement of their contents, constitute the author's own intellectual creation shall be protected as such by copyright" (art 3(1) of the Database Directive).
- **SGDR protection:** regardless of the originality in the selection or arrangement of their contents, databases may be protected under the SGDR if they show that "there has been qualitatively and/or quantitatively a substantial investment in either the obtaining, verification or presentation of the contents to prevent extraction and/or re-utilization of the whole or of a substantial part [...] of the contents of that database." (art 7(1) of the Database Directive)

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56 Case C-338/02 *Fixtures Marketing Ltd v Svenska Spel AB* [2004] ECR I-10497, para 28.

57 Case C-338/02 *Fixtures Marketing Ltd v Svenska Spel AB* [2004] ECR I-10497, para 27.

- ***Exceptions to the exclusive rights:*** Not only the granted rights, but also the exceptions to these exclusive rights change. Art. 6 of the Database Directive provides some optional limitations that may be added to the national law concerning copyright protected databases (Additional limitations and exceptions that can be found in other Directives/Treaties may apply). On the other hand, Art. 9 of the Database Directive provides the specific exceptions to the sui generis right.
- ***Term of protection:*** While the SGDR term of protection generally "shall expire fifteen years from the first of January of the year following the date of completion" (art 10 of the Database Directive), the copyright protection on original databases shall be, with some exceptions provided by law, the whole life of the author plus 70 years after his death (art 1 of the Term Directive).[58]

Why is it important to make such distinction?

Not only because the scope, duration and requirements are different, but because we can have cases where both rights coexists. Consider a database made of photographs, which the content selection was original and the obtaining of the content required substantial investment.

In this case, we would have at least three layers of rights under the non-personal data legal framework:

- **First layer**: photographs can be protected by copyright individually, regardless of being part of the database;
- **Second layer**: copyright protection to the database itself because of its original selection;
- **Third layer**: SGDR protection to the database because of the substantial investment employed in the content selection.

It is not uncommon that these three layers of rights are owned by different rightsholders with different interests and ways of licensing (if needed) their rights.

[58] Directive 2006/116/EC of the European Parliament and of the Council of 12 December 2006 on the term of protection of copyright and certain related rights [2006] OJ L 372/12.

3.2.4 Trade Secrets

What is considered a trade secret?

Being a trade secret is not necessarily connected to any characteristic of the information itself, but to measures that are employed in relation to it. In order to be considered "trade secret", the information must meet the following criteria:

(a) it is secret in the sense that it is not, as a body or in the precise configuration and assembly of its components, generally known among or readily accessible to persons within the circles that normally deal with the kind of information in question;
(b) it has commercial value because it is secret;
(c) it has been subject to reasonable steps under the circumstances, by the person lawfully in control of the information, to keep it secret.[59]

On the regional level, the protection conferred to Trade Secrets is regulated by Directive (EU) 2016/943 ('Trade Secrets Directive'). As commented when addressing other IP rights, other related directives, international treaties and the national laws on the subject matter should be considered, since national laws can be even more restrictive than the rules set out in the Trade Secrets Directive.[60]

What is the scope of the Trade Secrets Directive?

In order to properly address the scope of the Trade Secrets Directive, it is necessary to address the difference between lawful and unlawful acquisition, use and disclosure of trade secrets. This is because, the Directive 'lays down rules on the protection against the unlawful acquisition, use and disclosure of trade secrets.' (art 1(1) of the Trade Secrets Directive).

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[59] Art 2(1) of the Trade Secrets Directive. Directive (EU) 2016/943 of the European Parliament and of the Council of 8 June 2016 on the protection of undisclosed know-how and business information (trade secrets) against their unlawful acquisition, use and disclosure [2016] OJ L 157/1.

[60] According to the Trade Secrets Directive, in its Art. 1(1): '1. This Directive lays down rules on the protection against the unlawful acquisition, use and disclosure of trade secrets. Member States may, in compliance with the provisions of the TFEU, provide for more far-reaching protection against the unlawful acquisition, use or disclosure of trade secrets than that required by this Directive [...]'.

When the acquisition, use and disclosure of Trade Secrets is considered unlawful?

Below, we provide lists of practices that are considered lawful and unlawful acquisition, use and disclosure under the Trade Secrets Directive. As it was seen in the questions related to copyright, the rights provided in the Trade Secrets Directive also have exceptions, which can also be considered as legitimate uses, and are listed in the "lawful acquisition, use and disclosure" column.

Lawful acquisition, use and disclosure	Unlawful acquisition, use and disclosure
'independent discovery or creation' (art 3(1)(a) of the Trade Secrets Directive)	'unauthorised access to, appropriation of, or copying of any documents, objects, materials, substances or electronic files, lawfully under the control of the trade secret holder, containing the trade secret or from which the trade secret can be deduced' (art 4(2)(a) of the Trade Secrets Directive)
'observation, study, disassembly or testing of a product or object that has been made available to the public or that is lawfully in the possession of the acquirer of the information who is free from any legally valid duty to limit the acquisition of the trade secret' (art 3(1)(b) of the Trade Secrets Directive)	'any other conduct which, under the circumstances, is considered contrary to honest commercial practices' (art 4(2)(b) of the Trade Secrets Directive)
'exercise of the right of workers or workers' representatives to information and consultation in accordance with Union law and national laws and practices' (art 3(1)(c) of the Trade Secrets Directive)	'whenever carried out, without the consent of the trade secret holder, by a person who is found to meet any of the following conditions: (a) having acquired the trade secret unlawfully; (b) being in breach of a confidentiality agreement or any

	other duty not to disclose the trade secret; (c) being in breach of a contractual or any other duty to limit the use of the trade secret' (art 4(3) of the Trade Secrets Directive)
'any other practice which, under the circumstances, is in conformity with honest commercial practices' (art 3(1)(d) of the Trade Secrets Directive)	'whenever a person, at the time of the acquisition, use or disclosure, knew or ought, under the circumstances, to have known that the trade secret had been obtained directly or indirectly from another person who was using or disclosing the trade secret unlawfully within the meaning [of art 4(3) above]' (art 4(4) of the Trade Secrets Directive)
'required or allowed by Union or national law' (art 3(2) of the Trade Secrets Directive)	'The production, offering or placing on the market of infringing goods, or the importation, export or storage of infringing goods for those purposes, shall also be considered an unlawful use of a trade secret where the person carrying out such activities knew, or ought, under the circumstances, to have known that the trade secret was used unlawfully within the meaning [of art 4(3) above]' (art 4(5) of the Trade Secrets Directive)
Exceptions provided in Art. 5 'Member States shall ensure **that an application for the measures, procedures and remedies provided for in this Directive is dismissed** where the alleged acquisition, use or disclosure of the trade secret was carried out in any of the following	-

cases: (a) for **exercising the right to freedom of expression and information** as set out in the Charter, including respect for the freedom and pluralism of the media; (b) for **revealing misconduct, wrongdoing or illegal activity**, provided that the respondent acted for the purpose of protecting the general public interest; (c) disclosure by workers to their representatives as part of the **legitimate exercise by those representatives of their functions in accordance with Union or national law**, provided that such disclosure was necessary for that exercise; (d) for the purpose of **protecting a legitimate interest recognised by Union or national law**' (emphasis added)	

3.2.5 Non-personal data and public sector bodies

3.2.5.1 Open Data Directive

What is the Open Data Directive?

The Open Data Directive[61] aims to "promote the use of open data and stimulate innovation in products and services" by setting "*minimum rules*

[61] Directive (EU) 2019/1024 of the European Parliament and of the Council of 20 June 2019 on open data and the re-use of public sector information [2019] OJ L 172/56 (ODD – Open Data Directive).

governing the re-use and the practical arrangements for facilitating the re-use of" certain data.[62]

Which kind of data is covered by the ODD?

The data covered by ODD are the following:

(a) existing documents held by public sector bodies of the Member States (including executive, legislative and judicial bodies);
(b) existing documents held by public undertakings that are:
  (i) active in the areas defined in Directive 2014/25/EU on procurement by entities operating in the water, energy, transport and postal services sectors;
  (ii) acting as public service operators pursuant to Article 2 of Regulation (EC) No 1370/2007 on public passenger transport services by rail and road;
  (iii) acting as air carriers fulfilling public service obligations pursuant to Article 16 of Regulation (EC) No 1008/2008; or
  (iv) acting as Community shipowners fulfilling public service obligations pursuant to Article 4 of Regulation (EEC) No 3577/92;
(c) research data (see the definition below).

What is understood as 'research data' under the ODD?

Concerning the 'research data' referred in the ODD, these should be understood as "documents in a digital form, other than scientific publications, which are collected or produced in the course of scientific research activities and are used as evidence in the research process, or are commonly accepted in the research community as necessary to validate research findings and results".[63] It is clear from the Art. 2(1)(c) that the ODD does not apply to "documents for which third parties hold intellectual property rights".

What are the conditions for re-use of research data under the ODD?

The Directive does not establish a general obligation to allow re-use of documents produced by public undertakings and the decision to authorise re-use remains with the public undertaking concerned.[64] Nonetheless, it

62 ODD, art 1(1).

63 ODD, art 2(9)

64 ODD Recitql 26.

requires Member States to provide a legal framework that should allow the re-use of research data "for commercial or non-commercial purposes" if:

- The data are publicly funded and
- researchers, research performing organisations or research funding organisations have already made them publicly available through an institutional or subject-based repository.[65]

The uses allowed shall be carried out "in accordance with Chapters III and IV" of the ODD and additional factors must be taken into account, as is the case of "legitimate commercial interests, knowledge transfer activities and pre-existing intellectual property rights".[66]

It is important to highlight that, as a Directive, the ODD is not directly enforceable in the EU Member States, and a thorough analysis of the national policies and actions on Open Science should be carried out in order to ensure the legitimacy of the intended uses for a selected material. [67]

What are High-Value Datasets?

According to Art. 2(10) of the ODD

> means documents the re-use of which is associated with important benefits for society, the environment and the economy, in particular because of their suitability for the creation of value-added services, applications and new, high-quality and decent jobs, and of the number of potential beneficiaries of the value-added services and applications based on those datasets.

According to the Annex I of the ODD, the current thematic categories for the high-value datasets are the following: (i) Geospatial; (ii) Earth

65 ODD, art 10(2).

66 ODD, art 10(2).

67 According to art 10(1) of the ODD, "1. Member States shall support the availability of research data by adopting national policies and relevant actions aiming at making publicly funded research data openly available ('open access policies'), following the principle of 'open by default' and compatible with the FAIR principles. In that context, concerns relating to intellectual property rights, personal data protection and confidentiality, security and legitimate commercial interests, shall be taken into account in accordance with the principle of 'as open as possible, as closed as necessary'. Those open access policies shall be addressed to research performing organisations and research funding organisations.".

observation and environment; (iii) Meteorological; (iv) Statistics; (v) Companies and company ownership; (vi) Mobility. "Such specific high-value datasets shall be":

(a) available free of charge (with exceptions in certain cases pertaining to i) distortion of competition, ii) libraries, museums, archives, iii) substantial impact on the budget of the public sector body (see Article 14 para. 3-5 ODD)
(b) machine readable;
(c) provided via APIs; and
(d) provided as a bulk download, where relevant.[68]

The Commission shall adopt implementing acts (i) "laying down a list of specific high-value datasets belonging to the categories set out in Annex I" and that (ii) "may specify the arrangements for the publication and re-use of high-value datasets", which (iii) "shall be compatible with open standard licences."[69]

What happens if the research (or other) data covered by the rules of the ODD are subject to IP rights owned by third-parties?

Art 1(2)(c) of the ODD is clear when it affirms that the Directive does not apply to "documents for which third parties hold intellectual property rights". Therefore, considering that "certain categories of data, such as commercially confidential data, data that are subject to statistical confidentiality and data protected by intellectual property rights of third parties, including trade secrets and personal data, in public databases are often not made available, not even for research or innovative activities in the public interest",[70] comments must be made on the Data Governance Act that, among other objectives, aims to provide "conditions for the re-use, within the Union, of certain categories of data held by public sector bodies".[71]

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68 ODD, art 14 (1).

69 ODD, art 14 (1).

70 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 (2022) OJ L 152/1 (Data Governance Act), rec 6.

71 DGA, Art 1(1)(a).

3.2.5.2 Digital Services Act[72]

How does the DSA facilitate data access for research organisations and researchers?

Among numerous provisions increasing transparency of intermediary services and online platforms, a major contribution is made by Article 40 (4) of the DSA which allows vetted researchers meeting pre-defined criteria (including acting in a not-for-profit or public interest mission context – see below) to gain access to the data of Very Large Online Search Engines (VLOSEs) and Very Large Online Platforms (VLOPs), for the purposes of conducting research into the relevant systemic risks and assess how effective the platform's actions are in mitigating them.

What systemic risks can justify access by vetted researchers?

Per Article 34 DSA, the systemic risks carried by VLOPs and VLOSEs may pertain to (i) dissemination of illegal content; (ii) any actual or foreseeable negative impact on fundamental rights,[73] civic discourse, electoral processes, public security, gender-based violence, the protection of public health and minors, as well as (iii) serious negative consequences to physical and mental well-being.

What are the eligibility criteria for researchers to gain access to data?

Upon their substantiated request, researchers must be vetted by the Digital Services Coordinator of establishment for the VLOP or VLOSE in question, for compliance with criteria set out in Article 40(8) DSA, such as affiliation to a research organisation (within the meaning of Article 2 CDSM), independence from commercial interests, their ability to meet confidentiality requirements, proportionality of their request, the relevance

[72] 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) (Text with EEA relevance)

[73] Under Article 34 (1) DSA, this includes, in particular, the fundamental right to human dignity (Article 1 of the Charter), to respect for private and family life (Article 7 of the Charter), to the protection of personal data (Article 8 of the Charter), freedom of expression and information, including the freedom and pluralism of the media (Article 11 of the Charter), to non-discrimination (Article 21 of the Charter, to respect for the rights of the child (Article 24 of the Charter) and to a high level of consumer protection (Article 38 of the Charter).

of their research to identifying and mitigation of the relevant risks, as well as their commitment to make the results publicly available for no charge.

What are the eligibility criteria for research organisations to benefit from the Art. 40 data access regime?

The research organisation must fulfil the definition of Article 2 of the CDSM Directive, which encompasses universities, including their libraries, research institutions or any other entity, the primary goal of which is to conduct scientific research or to carry out educational activities involving also the conduct of scientific research – either not-for-profit, or pursuant to a public interest mission recognised by a Member State. Any entities exercising power over the organisation must also not enjoy access to the results of the research on a preferential basis[74].

Does the DSA create any risks or obligations to researchers and research organisations?

For research organisations acting as *recipients* (but not providers) of intermediary services (e.g. cloud hosting, virtual classrooms), foreseeable risks will likely be limited beyond a potential price increase due to the stronger compliance requirements on providers.

At the same time, the question of whether RPOs could be considered as *providers* of intermediary services under the DSA is more complex. At least theoretically in some cases, such services could meet the criterion of being 'normally provided for remuneration'[75]. This would trigger applicability of the DSA rules for providers of intermediary services, with the implications depending on the qualification of the service as 'caching', 'hosting' or 'mere conduit'[76], likely carrying significant compliance costs and incentivising increased outsourcing.[77] However, this assessment would need to be

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74 Article 2 (1) CDSM.

75 Article 1 (1) b) of Directive (EU) 2015/1535 referenced by Article 3 (a) DSA.

76 Article 3 (g) DSA.

77 European Commission, Directorate-General for Research and Innovation, Improving access to and reuse of research results, publications and data for scientific purposes – Study to evaluate the effects of the EU copyright framework on research and the effects of potential interventions and to identify and present relevant provisions for research in EU data and digital legislation, with a focus on rights and obligations, Publications Office of the European Union, 2024, https://data.europa.eu/doi/10.2777/633395, p. 276.

performed on a case-by-case basis, with the result depending on the entire set of circumstances.[78]

3.2.5.3 Data Act[79]

What data does the Data Act apply to?

The Data Act covers unprocessed data created by the use of IoT products (such as e.g. telemetry data generated by a connected car's sensors) and related services, recorded intentionally or resulting indirectly from the users' actions or inaction, either in raw form ('source' or 'primary' data) or pre-processed for the purpose of making them understandable and useable prior to subsequent processing and analysis[80]. The data needs to be accompanied by the relevant metadata that is necessary to interpret and use the data in question.

Exclusions from scope include:

- 'derivative' data (created or inferred on the basis of primary data, such as by making inferences from a number of sensors using proprietary algorithms which could be subject to intellectual property rights), as well as
- content (textual, audio or audiovisual) which is typically covered by copyright, as well as data that such sensor-equipped connected products generate when the user records, transmits, displays or plays content.

What are the categories of data under the Data Act?

- Readily available data: that which is lawfully obtained by the data holder from the connected product of related service, by means of product design and/or a contract with the user or related services without disproportionate effort going beyond a simple operation;
- Data that is directly accessible from on-device data storage or from a remote server to which the data are communicated;

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78 For a more comprehensive discussion, see ibid., pp. 265 et seq.

79 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)

80 Article 1 (2) a) in connection with Recital 15 DA.

- Metadata (a structured description of the contents or the use of data facilitating the discovery or use of that data).

Who are the main stakeholders under the Data Act?

The Data Act addresses the relationship between:

- *data holders* (who may be e.g. manufacturers or sellers of connected devices),
- *users* of connected devices (natural or legal persons owning or holding of temporary usage rights, receiving the related services) as well as
- *data recipients* (natural or legal persons to whom the data is made available, including on request of the user (example: a third-party repair shop receiving access to onboard data in a connected vehicle).
- *Public Sector Bodies* (PSB's) meaning State authorities, bodies governed by State laws or associations formed by one or more such entities.

How can researchers benefit from the Data Act to gain access to data?[81]

a) **As users**. Under Article 4 of the Data Act, rights of data access are granted to users of connected products. When the data cannot be accessed directly from the product or related service, it is to be made available by data holders on a "simple request", along with the necessary metadata, and without undue delay. Researchers and research organisations can benefit from this framework insofar as they qualify as users of connected devices under the Data Act.

b) **As data recipients**. Under Article 5, users can request the data holder to grant access to readily available data, along with the relevant metadata necessary to interpret and use those data, to a third party which can also be a researcher or a research organisation. In case of SMEs and not-for-profit research organisations that do not have linked or partnered enterprises that do not qualify as SMEs, any compensation for making data available cannot exceed costs incurred in making the data available, such as the formatting of data, dissemination via electronic means and storage.[82]

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81 For a comprehensive analysis, please refer to European Commission (2024), pp. 285 et seq.

82 Article 9 (4) DA.

c) **As recipients of data obtained obtained in context of exceptional need.** Data that is obtained by Public Sector Bodies, the Commission, the European Central Bank in cases of exceptional need, such as a public emergency with no other ways of timely and effective means of obtaining the data, or (exclusively for non-personal data) when the data is indispensable to perform a legally mandated specific task carried out in the public interest,[83] may then be shared with individuals or organisations in view of carrying out scientific research or analytics compatible with the purpose for which the data was requested.[84]

3.2.5.4 Data Governance Act[85]

What is the nature of data covered by the DGA?

For the purposes of this document, and focusing on the data that is held by Public Sector Bodies (PSBs) and could be (re)used, the Act applies to data held by public sector bodies which are protected on grounds of:

a) commercial confidentiality, including business, professional and company secrets;
b) statistical confidentiality;
c) the protection of intellectual property rights of third parties; or
d) the protection of personal data, insofar as such data fall outside the scope of Directive (EU) 2019/1024.[86]

Does the DGA interfere in the ownership or exercise of the IPRs by Public Sector Bodies?

No. The DGA "should neither affect the existence or ownership of intellectual property rights of public sector bodies nor limit the exercise of those rights in any way".[87] Therefore, rules contained therein should not go

83 Article 15 DA.

84 Article 21 (1) a) DA.

85 On the matter, see Baloup, J., E Bayamlıoğlu, A Benmayor, C Ducuing, L Dutkiewicz, T Lalova, Y Miadzvetskaya, and B Peeters, White Paper on the Data Governance Act (2021) CiTiP Working Paper https://www.law.kuleuven.be/citip/blog/citip-white-paper-on-the-data-governance-act/.

86 Art. 3 (1) DGA.

87 DGA, rec 17.

against the national law, EU law on IPRs and international treaties on the subject matters (e.g. Berne Convention, TRIPS and the WCT).[88]

The main idea under the DGA is that PSBs exercise their IP rights (including the SGDR) in a way to facilitate re-use.[89]

Then, which are some of the main contributions from the DGA when it comes to IPRs?

One of them is the establishment of the European Data Innovation Board, which has amongst its tasks the duty to

> advise and assist the Commission with regard to developing consistent guidelines on how to best protect, in the context of this Regulation, commercially sensitive non-personal data, in particular trade secrets, but also non-personal data representing content protected by intellectual property rights from unlawful access that risks intellectual property theft or industrial espionage[90]

The DGA also provides a set of conditions for (re)use of protected data that may be adopted by Public Sector Bodies and which encompasses, among others, that the access and (re)use of data is carried within a 'secure processing environment'.[91] For the purposes of the DGA,

> "secure processing environment" means the physical or virtual environment and organisational means to ensure compliance with Union law, such as Regulation (EU) 2016/679, in particular with regard to data subjects' rights, intellectual property rights, and commercial and statistical confidentiality, integrity and accessibility, as well as with applicable national law, and to allow the entity providing the secure processing environment to determine and supervise all data processing actions, including the display, storage, download and export of data and the calculation of derivative data through computational algorithms.[92]

88 Id

89 DGA, recs 17 and 18.

90 DGA, art 30(d)

91 DGA, art 5(3)(b)(c).

92 DGA, art 2(20).

3.2.5.5 AI Act

Does the AI Act establish any specific regime or exemptions for research?

AI systems or AI models which are specifically developed and put into service **for the sole purpose of scientific research and development** are explicitly removed from scope of the AI Act.[93] However, this is likely to be interpreted narrowly, ensuring that any other AI system that may be used for the conduct of any research and development activity remains subject to the provisions of the Act.[94]

What are the compliance burdens for researchers working on/with AI?

While the AIA is still a new law at the time of drafting this document, existing literature already allows to formulate expectations as regards the potential compliance burdens that it may create for researchers. The following key dimensions need to be mentioned:

1. AI systems or AI models which are specifically developed and put into service **for the sole purpose of scientific research and development** are not covered by the AI Act.[95] However, this is likely to be interpreted narrowly, ensuring that any other AI system that may be used for the conduct of any research and development activity remains subject to the provisions of the Act.[96]

2. In all other cases, **researchers deploying AI in their research** must be particularly mindful of:

    a) *the prohibitions* of Article 5, particularly those involving the use of AI systems materially distorting (or likely to distort) a person's behaviour including via subliminal influence, exploitation of their age or disability-related vulnerabilities, or via intentional manipulation of their behaviour, putting them at risk of significant

93 Article 2 (6) AIA.

94 Recital 25 AIA.

95 Article 2 (6) AIA.

96 Recital 25 AIA.

harm.[97] In narrowly defined circumstances, this prohibition is not to affect research that is being conducted for legitimate purposes and

- does not amount to use of the AI system in human-machine relations that exposes natural persons to harm, and
- is carried out in accordance with recognised ethical standards for scientific research.[98]

b) the additional obligations that may apply to deployers of an AI system that is classified as high-risk which are applicable:

- merely by virtue of using a high-risk system,[99] and/or
- by introducing substantial modifications or modifying the intended purpose of such a system (or any other system that becomes high-risk as a result) which is tantamount to becoming the provider of this system[100] under the AIA, triggering applicability of the extensive risk management, monitoring and documentation duties envisaged under the Act.

Is there a risk of the AI Act imposing limits on research?

While it may be said that the AI Act's prohibitions create hard lines that could theoretically rule out certain uses of AI in research, it is doubtful whether - in practice - any use cases so unethical as those prohibited under Article 5 AIA (e.g. subliminal behavioural manipulation) were available to researchers before the Act's arrival.

More practical limits may potentially arise in case of increase of compliance costs arising from dealing with high-risk AI systems, particularly where the deployer fulfils the criteria for being considered a provider under Article 28 AIA.

Is there a separate regime for Open Source AI in the AI Act?

The AI Act contains a broad exception removing from its scope a considerable part of AI systems released under free and open-source

97 Article 5 (1) a) and b) AIA.

98 Recital 16 AIA.

99 Article 26 AIA.

100 Article 25 AIA.

licences. The exception applies as long as the AI system is not one listed under Article 5 (prohibitions) Article 50 (direct interaction with humans, generative AI including content manipulation, biometric categorisation, emotional recognition) or the provisions on high-risk AI.[101] However, in any case, AI systems' developers '*should be encouraged to implement widely adopted documentation practices, such as model cards and data sheets, as a way to accelerate information sharing along the AI value chain, allowing the promotion of trustworthy AI systems in the Union*'.[102]

General-purpose AI models without systemic risk, released under a free and open-source licence, making publicly available their parameters (including the weights, information on the model architecture, usage etc.) can benefit from exceptions as the AI Act's transparency-related requirements imposed on general-purpose AI models, save for the need to produce a summary about the content used for model training and the obligation to put in place a policy to comply with Union copyright law, in particular to identify and respect opt-outs from model training under Article 4(3) of the Copyright Directive (EU) 2019/790.[103]

Lastly, general-purpose, high-impact AI systems planned for an open-source release, which which satisfy the requirements for the presumption to be general-purpose AI models with systemic risk, must be reported to the AI Office within two weeks after the requirements are met, along with any information that would justify the system not to be classified as bearing a systemic risk.[104]

3.2.5.6 Data under EU-funded projects

What if the data I intend to use were generated by EU-funded projects?

Depending on the grant agreement, there may be mandatory practices related to Open Science, and therefore, Open Access to be carried out by the beneficiary(ies). As an example, Projects funded under the Horizon

[101] Article 2 (12) AIA.

[102] Recital 89 AIA.

[103] See Article 53 (1) and (2), Recital 104 AIA.

[104] Article 52 AIA.

Europe Program must comply with the obligations provided in the Grant Agreement and, therefore, with the "open access prior obligation".[105]

To provide further illustration, and when it comes to scientific publications, according to the rules contained on Annex 5 of the Annotated Grant Agreement (Draft Version) and concerning Art. 17 of such Agreement,

> The beneficiaries must ensure open access to peer-reviewed scientific publications relating to their results. In particular, they must ensure that:
>
> - at the latest at the time of publication, a machine-readable electronic copy of the published version or the final peer-reviewed manuscript accepted for publication, is deposited in a trusted repository for scientific publications
>
> - immediate open access is provided to the deposited publication via the repository, under the latest available version of the Creative Commons Attribution International Public Licence (CC BY) or a licence with equivalent rights; for monographs and other long-text formats, the licence may exclude commercial uses and derivative works (e.g. CC BY-NC, CC BY-ND) and
>
> - information is given via the repository about any research output or any other tools and instruments needed to validate the conclusions of the scientific publication. Beneficiaries (or authors) must retain sufficient intellectual property rights to comply with the open access requirements[106]

The document also provides further duties regarding metadata and the data involved in the research.

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[105] Commission, 'What is the "open access prior obligation"?' (Funding & Tender Opportunities, 2018c) <https://ec.europa.eu/info/funding-tenders/opportunities/portal/screen/support/faq/22153;type=0,1;categories=;tenders=;programme=null;keyword=;freeTextSearchKeyword=%20prior%20obligation;matchWholeText=true;period=null;status=0;sortQuery=publicationDate;faqListKey=faqSearchTablePageState>

[106] Commission, EU Grants AGA – Annotated Grant Agreement: EU Funding Programmes 2021-2027 (v.1 Draft, 01 Apr 2023), https://ec.europa.eu/info/funding-tenders/opportunities/docs/2021-2027/common/guidance/aga_en.pdf accessed 06 apr 2023.

4 Ethics in research and open science

Addressing ethical issues is always a complex undertaking. One of the reasons is that ethical issues may vary according to the field of research (e.g. research involving human cells may raise different ethical issues than a research using artificial intelligence systems). Another one is relating to the fact that ethical issues and, therefore, guidelines/codes of conduct can be far more dynamic than legal texts. There are multiple, and different, normative theories and principles related to each one of them.[107] Vedder (2019, 2) also highlights that "[...] ethics – to the degree that it is not incorporated in the law – does not enjoy the same status as to its legitimacy and authority as the law does". And, finally, the term "ethics" can be understood in various ways:

> 'Ethics' may refer to (A) the concrete feelings, opinions, and arguments in moral matters, existing in the minds and the hearts of people and materializing in their actions, policies etc. It may, however, also refer to (B) the academic discipline that methodically reflects on moral matters, sometimes also referred to as moral philosophy or philosophical ethics. In the latter sense, ethics may be (B1) an *empirical undertaking*, mainly describing what people think and feel, how they reason and judge concerning good or bad intentions, actions, lives etc. – in sum, a branch of philosophy overlapping to a large degree with social sciences – or it may be (B2) *critically normative*, by providing proposals for intentions, actions and ways of life, or their assessment.[108]

In view of the nebulosity of the term and the wide array of possible understandings, this document will necessarily seek to provide a narrowed-down overview of the aspects relevant to Open Science while avoiding an exhaustive discussion of all identifiable ethical issues in other research fields (see, e.g., Declaration of Helsinki[109]; the UNESCO Universal

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107 For example, deontological, utilitarian and communitarian theories. Anton Vedder, 'Mind the gap. Managing the expectations of legal scholars turning to ethics for help where the law does not yet provide answers' In: Centre for IT & IP Law (ed.) Rethinking IT and IP Law. Celebrating 30 Years CiTiP Cambridge/Antwerp: Intersentia, 2019, pp. 305-312 https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3450544.

108 Vedder (2019) 2.

109 https://www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principles-for-medical-research-involving-human-subjects/

Declaration on Bioethics and Human Rights)[110] and environments (e.g. EAG Report "Towards a digital ethics"),[111] with the employment of specific technologies (e.g. the Ethical Guidelines for Trustworthy AI).[112]

Maintaining the focus on Open Science, this section will present some of the main documents that address the relevant ethical issues. They will be briefly described, and a set of additional resources about them and their relationship with OS will be provided. Even within this narrower approach, the documents addressed here are just a part of a whole framework of guidelines, codes of conduct and other instruments that could be categorized under different ways, for example, according to their scope, form, target group, and content.[113]

4.1 FAIR Principles

The FAIR principles are a set of guidelines that can be employed to make data Findable, Accessible, Interoperable and Reusable (Wilkinson et al., 2016):

FAIR Principles	***Description***
Findable	"F1. (meta)data are assigned a globally unique and persistent identifier F2. data are described with rich metadata (defined by R1 below) F3. metadata clearly and explicitly include the identifier of

[110] World Medical Association (WMA), 'WMA Declaration of Helsinki – Ethical Principles for Medical Research Involving Human Subjects' (6 Sep 2022) https://www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principles-for-medical-research-involving-human-subjects/. UNESCO, 'Universal Declaration on Bioethics and Human Rights' (19 Oct 2005) https://www.unesco.org/en/legal-affairs/universal-declaration-bioethics-and-human-rights?hub=66535.

[111] European Data Protection Supervisor, Ethics Advisory Group, JP Burgess et al., 'Towards a digital ethics' (2018) https://edps.europa.eu/sites/edp/files/publication/18-01-25_eag_report_en.pdf.

[112] European Commission, High-Level Expert Group on Artificial Intelligence, 'Ethics Guidelines for Trustworthy AI' (2018) https://digital-strategy.ec.europa.eu/en/library/ethics-guidelines-trustworthy-ai.

[113] Sutrop, Parder and Juurik (2019)

	the data it describes F4. (meta)data are registered or indexed in a searchable resource."
Accessible	"A1. (meta)data are retrievable by their identifier using a standardized communications protocol A1.1 the protocol is open, free, and universally implementable A1.2 the protocol allows for an authentication and authorization procedure, where necessary A2. metadata are accessible, even when the data are no longer available."
Interoperable	"I1. (meta)data use a formal, accessible, shared, and broadly applicable language for knowledge representation. I2. (meta)data use vocabularies that follow FAIR principles I3. (meta)data include qualified references to other (meta)data"
Reusable	"R1. meta(data) are richly described with a plurality of accurate and relevant attributes R1.1. (meta)data are released with a clear and accessible data usage license R1.2. (meta)data are associated with detailed provenance R1.3. (meta)data meet domain-relevant community standards".

Source: Wilkinson et al. (2016)

There is a substantial amount of relevant resources on the FAIR principles: projects, deliverables, scientific articles, courses, etc. For the purpose of this document, the article "The FAIR Guiding Principles for scientific data management and stewardship"[114] and related materials, initiatives aiming to translate the principles into practice like GO FAIR[115] and FAIRsFAIR[116], and

[114] https://rdcu.be/dQ6QK

[115] https://www.go-fair.org/

[116] https://www.fairsfair.eu/the-project

EU publications like "Turning FAIR into reality"[117] and "Digital skills for FAIR and Open Science"[118] are relevant resources on the matter.

4.2 Responsible Research and Innovation (RRI)

Responsible Research and Innovation (RRI) aims to "create a society in which R&I work towards sustainable, ethically acceptable, and socially desirable outcomes, addressing several agendas needed for a fair and just society".[119] Under the RRI Tools[120] and ORBIT[121] projects, the six main aspects of RRI would be "Ethics, Science Education, Gender Equality, Open Access, Governance and Public Engagement."[122]

On the ethical part of it, it is worth highlighting that

> When it comes to Responsible Research and Innovation (RRI), the core ethical endeavour is to achieve its integration across the entire research and innovation (R&I) process. This process can be roughly divided into four phases: policy making and agenda setting, funding call formulation, project definition and proposal writing, and project execution and evaluation. Integrating ethics into these phases requires continuous orientation, reflection and deliberation on the decisions, actions and values at stake.[123]

Many documents and projects address RRI practices. Some of them are listed below:

- ORBIT RRI: https://www.orbit-rri.org/

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117 European Commission, Directorate-General for Research and Innovation, *Turning FAIR into reality : final report and action plan from the European Commission expert group on FAIR data*, Publications Office, 2018, https://data.europa.eu/doi/10.2777/1524

118 European Commission, Directorate-General for Research and Innovation, Manola, N., Lazzeri, E., Barker, M., et al., *Digital skills for FAIR and Open Science : report from the EOSC Executive Board Skills and Training Working Group*, Manola, N. (editor), Lazzeri, E. (editor), Barker, M. (editor), Kuchma, I. (editor), Gaillard, V. (editor), Stoy, L. (editor), Publications Office, 2021, https://data.europa.eu/doi/10.2777/59065

119 RRI Tools, 'Training on RRI' https://rri-tools.eu/training/about

120 https://rri-tools.eu

121 https://orbit-rri.org/resources/keys-of-rri/

122 ORBIT, 'The Keys of Responsible Research and Innovation' (n.d.) https://www.orbit-rri.org/resources/keys-of-rri/

123 RRI Tools, 'How to promote research integrity' https://rri-tools.eu/how-to-pa-ethics#menu-anchor-id2-content

- RRI Tools: https://rri-tools.eu/ethics
- WBC-RRI – Responsible research and Innovation in the Western Balkans: https://wbc-rri.net/
- "Responsible research and innovation (RRI), science and technology" report: https://op.europa.eu/en/publication-detail/-/publication/ee9bacdf-fdad-46eb-8cd8-32879e310191/language-en/format-PDF/source-283914549.

4.3 European Code of Conduct for Research Integrity

Codes/guidelines on ethics vary across different fields of expertise. In research, for example, the European Code of Conduct for Research Integrity[124] is one of the main resources. If personal data is processed, some best practices related to ethics may also apply (see, eg, European Commission (DG Research and Innovation) unofficial guidelines on *Ethics and data protection.*[125]

The European Code of Conduct for Research Integrity is a code of conduct made available by the All European Academies (ALLEA) with the main objectives of "[serving] the research community as a framework for self-regulation" and to help realise the "basic responsibility of the research community[, which] is to formulate the principles of research, to define the criteria for proper research behaviour, to maximise the quality and robustness of research, and to respond adequately to threats to, or violations of, research integrity".[126]

In the document, good research practices are described in multiple contexts, these being: "Research Environment; Training, Supervision and Mentoring; Research Procedures; Safeguards; Data Practices and

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124 https://allea.org/code-of-conduct/

125 Commission (Directorate-General for Research and Innovation) "Ethics and data protection" https://ec.europa.eu/info/funding-tenders/opportunities/docs/2021-2027/horizon/guidance/ethics-and-data-protection_he_en.pdf accessed 16 Aug 2024; European Commission, Ethics and data protection, DG Research & Innovation RTD.03.001- Research Ethics and Integrity Sector, https://ec.europa.eu/info/funding-tenders/opportunities/docs/2021-2027/horizon/guidance/ethics-and-data-protection_he_en.pdf

126 ALLEA (2017, 3).

Management; Collaborative Working; Publication and Dissemination; Reviewing, Evaluating and Editing".[127]

From the analysis of the good practices recommended in different contexts, it is possible to clearly identify OS-related practices in almost all the contexts mentioned above, as it can be seen from the table below:

Context	***OS-related good practices***
Research Environment	"Research institutions and organisations reward open and reproducible practices in hiring and promotion of researchers."
Research Procedures	"Researchers publish results and interpretations of research in an open, honest, transparent and accurate manner, and respect confidentiality of data or findings when legitimately required to do so."
Data Practices and Management	"Researchers, research institutions and organisations ensure 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 Re-usable) for data management."
Collaborative Working	"All partners in research collaborations agree at the outset on the goals of the research and on the process for communicating their research as transparently and openly as possible."
Publication and Dissemination	"Authors ensure that their work is made available to colleagues in a timely, open, transparent, and accurate manner, unless otherwise agreed, and are honest in their communication to the general public and in traditional and social media."
Reviewing, Evaluating and Editing	"Researchers review and evaluate submissions for publication, funding, appointment, promotion or reward in a transparent and justifiable manner"

Source: ALLEA (2017, 5-8)

The document also provides fundamental principles of research integrity:

[127] ALLEA (2017, 5).

- ***Reliability*** in ensuring the quality of research, reflected in the design, the methodology, the analysis and the use of resources.
- ***Honesty*** in developing, undertaking, reviewing, reporting and communicating research in a transparent, fair, full and unbiased way.
- ***Respect*** for colleagues, research participants, society, ecosystems, cultural heritage and the environment.
- ***Accountability*** for the research from idea to publication, for its management and organisation, for training, supervision and mentoring, and for its wider impacts.[128]

4.4 Responsible Open Science for Europe (ROSiE)

ROSiE was a three-year project funded by HORIZON2020. Its mission was to co-create, alongside all related stakeholders, a set of novel practical tools to foster responsible Open Science and citizen science. One of the core aims was to address the relevant challenges in relation to research ethics (RE) and integrity (RI) with a view to establishing OS in the current European research environment and the existing EU frameworks such as the PSI Directive, R&I Framework, ERA, as well as the European Commission's eight ambitions on OS. One of the ROSiE's key contributions was its interdisciplinary knowledge hub[129] to support open approaches in science and research, while complying with relevant legal frameworks and ethical standards.

Based on a mapping of existing Open Science public policies across Europe[130], the ROSiE project produced guidelines on ethical and responsible Open Science. The General Guidelines on Responsible Open Science[131] (Policy Document Complementing the European Code of Conduct for Research Integrity (ECoC), have the aim of providing guidance on responsible conduct of Open Science in everyday research practice, following established ethical and integrity principles and values. While

128 ALLEA (2017, 4)

129 https://rosie-project.eu/rosie-knowledge-hub/

130 https://rosie-project.eu/wp-content/uploads/2024/02/WP05-D5.1-Report-on-existing-policies-and-guidelines.pdf

131 https://rosie-project.eu/wp-content/uploads/2023/09/WP05-D5.3-Policy-document-complementing-the-ECoC-FINAL.pdf

applying primarily to research, the Guidelines may also be suitable to processes leading to innovation.

Building on the General Guidelines, the ROSiE project developed Discipline-related Guidelines To implement Responsible Open Science in Europe[132] aiming to equip researchers with practical tools and guidance necessary to navigate the complexity of Open Science. In observance of the diverse characteristics of different fields of research, these guidelines aim to increase the uptake of OS in line with the highest standards of good scientific practice and the principles of research ethics and integrity, in accordance with researchers' own disciplines' requirements and specificities. Separate sets of guidelines are developed for the following scientific disciplines:

- Health and Life Sciences;
- Humanities;
- Natural Sciences, and
- Social Sciences.

For each of the identified disciplines, ROSIE's proposed framework addresses the following areas:

- Research Environment and Infrastructures;
- Protection of Research Participants, the Environment, Ecosystems, and Cultural Heritage;
- Open and Reproducible Research Practices, including:
    - Open research practices;
    - Open data:
    - Open methods and tools;
    - Open Access publication,
- Researcher Evaluation;
- Citizen Science;
- Training and Education;
- Inclusivity.

[132] https://rosie-project.eu/wp-content/uploads/2024/03/WP05-D5.4-Discipline-Related-guidelines_Disclaimer.pdf

5 Conclusions

Devised to support the roles of Policy Makers and Civil Servants in the area of policy, this document is meant to serve as a compendium bringing together relevant information and ready-made templates to enable a comfortable level of awareness of matters of personal data protection, intellectual property rights, data regulation and ethics.

Gaining this awareness is a useful stepping stone in performing policy making and other public administration roles with a view to strengthening and protecting the democratic society. The growing complexities of the digital reality make this task a particularly difficult one – rendering it all the more important for Civil Servants and Policy Makers to be capable of acting in full independence of narratives of any stakeholders with a vested interest in the course of their work.

Understanding, promoting, supporting and implementing Open Science programs and practices forms an important part in preventing commodification and commercialisation of science, facilitating further research, preserving democratic values in access to resources and the outcomes of scientific work. Whenever working with researchers and acting as researchers themselves, Policy Makers and Civil Servants have the power to support and strengthen Open Science. This document aims to help them along the way.

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Appendix A: Infographs

This Appendix includes the list of infographs used as illustrations in Deliverable 3.7. Full-size infographs are available on Zenodo:

https://zenodo.org/records/13467302/files/D3.7 - infographs.pdf

a) Intellectual Property Rights: Relationship between Directives, National Laws and International Treaties
b) EU Legal Framework on Data
c) Legal Bases of Data Processing
d) Principles of Personal Data Protection
e) Material and Territorial Scope of the GDPR
f) Rights of the Data Subject

Appendix B: Practical materials and templates

This Appendix includes a list of practical handouts to be shared with addressees of training and teaching sessions.[133] The templates are designed to prevent common errors and misconceptions in designing privacy policies, while remaining adaptable to specific circumstances.

The handouts document is available on Zenodo:
https://zenodo.org/records/13467302/files/D3.7 - handouts.zip

a) Data Protection Policy
b) General information on the treatment of personal data for the project
c) Table - purpose of processing: Scientific Research
d) Questionnaire Privacy Statement
e) Table - purpose of processing: Communication and Dissemination
f) Social Media Policy
g) Information on the treatment of personal data for Stakeholders
h) Informed consent for stakeholders
i) Informed consent for speakers invited to conventions and events
j) Informed consent of conventioneers/persons attending events
k) Informed consent of conventioneers/persons attending events GDPR

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[133] Used by kind permission from authors. The original document is also available on Zenodo: Colcelli, V., Cippitani, R., Brizioli, S., & Langella, A. (2024). How to write a Policy Privacy in a Research Project (version 1.0). Zenodo. https://doi.org/10.5281/zenodo.12820200

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