EOSC-Pillar

# Legal Compliance Guidelines for Researchers: **a Checklist**

## Authors

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## Disclaimer




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# Introduction

**Please note :**

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**In Acrobat Reader Go to "Preferences", then "Forms" and deactivate the "show border hover color for fields" option.**

## Phase1
Research Proposal

## Phase2
Research Implementation

## Phase3
Research review

This document provides a guideline in the form of checklists to help researchers comply with the legal requirements of publishing, sharing and integrating research data. In particular the challenges raised by intellectual property rights, data protection laws, and regulations on non-personal data are addressed. The purpose of the guideline is to promote the implementation of FAIR principles beyond their original scope, and to lay down the conditions for the effective realization of Open Data and Open Science policies.

The guidelines are valid for all EU member states. For a more in-depth explanation and background material please refer to the latest version of the **Legal and Policy Framework and Federation Blueprint** report (DOI: https://doi.org/10.5281/zenodo.5647948)

By leveraging regulatory flexibilities and taking into account legitimate restrictions to access research products, the checklists aim at:

A. Guiding researchers in the management of research data, or more generally, research outputs,
B. Promoting best practices to achieve Findability, Accessibility, and Interoperability of research data by focusing on the removal of unnecessary restrictions to reuse and open access to published products and facilitating the convergence of national solutions.

Checklists for research infrastructures accompany researchers through the life cycle of a research project and help them deal with legal constraints while adopting an efficient approach to leverage regulatory enablers. They follow the basic phases of every research project: proposal, implementation and review phase. Depending on whether personal data is part of the research each phase accompanies a section with guidelines on data protection.

You can find the official PDF of the Regulation (EU) 2016/679 (General Data Protection Regulation) as well as the current version of the GDPR regulation at this web site https://gdpr-info.eu.

# Phase 1

## Research Proposal

The research proposal phase covers the early conception of a research project. The checklist generally refers to the preparation of a research proposal, but it may also be applied to any initial planning that precedes the actual start of research activities.

### Intellectual Property Rights (IPR)

When drafting a proposal or planning joint research:

#### Check whether there is background information, data and intellectual property rights brought into the project. More specifically

- ◯ Clarify who brings what
- ◯ Identify the member state law applicable to each background material. Pay particular attentionto the territorial applicability of each right
- ◯ Make sure to secure clearance for each use by
  - Obtaining any authorisation needed for re-use and protection of derived data and other intellectual outputs,
  - Agree on rules of ownership attribution on derived data and other intellectual outputs.
- ◯ Aim at avoiding secrecy and at allowing re-use

#### Define Clearly

- ◯ The ownership and/or co-ownership of each research output stemming from
  - The use and re-use of pre-existing background information, data and IPRs,
  - Single or joint research activities within the framework of the project,
  - Single or joint research activities partially within OR outside the framework of the project, if building or depending on project activities.
- ◯ The legal regime applicable to each research output, with particular regard to territoriality and cross-border activities
- ◯ The forms of exploitation and degree of openness vs closeness envisioned, in light of OA and OS goals
  - Make sure to secure sufficient funding for OA/OS or to identify reliable free outlets and channels for dissemination.
- ◯ Liaise with your Technology Transfer Office (TTO) or offices in charge of legal matters, to lay down internal processes for the protection and management of Intellectual Capital (IC) stemming from the project
  - Make sure that your TTO or other office is aware of FAIR principles, and OA/OS best practices.

# Phase 1
## Research Proposal

### Data Protection

If you process any information that identifies a human person, please follow this checklist. If you cannot answer one (or any) of these questions, please, deal with your Data Protection Officer (DPO) or consider that it could be useful to appoint an ethics advisor and/or include knowledgeable staff.
If you are going to process either general or special categories of data, be aware to organise your data flows as follows and make sure you select which categories of data you are going to process.

#### If you are processing special categories of data, please check whether or not you will need the following safeguards

◯ To appoint a DPO and/or an ethical advisor

◯ With DPO and/or ethical advisor and/or competent staff in your entity/organisation, to identify the applicable ethical-legal framework according to the means and purposes of your data processing applied to your research

◯ To check if you will need approval from the competent ethics committee with your entity/organisation. In particular, it could be

- Binding according to the nature of the processed data and the applicable national implementation of article 89 GDPR.
- Binding according to the ground of vulnerability of data subjects (eg. children, according to possible standards/ guidelines applicable to your research).
- Kindly suggested because it is often required to validate your research by target journals and/or the funding entity/ organisation.

◯ To receive the approval of the competent ethics committee

◯ To collect the consent to process data in addition to the informed consent (infra) and to store them for a specific time

◯ To appoint a technician to pseudonymise data

◯ To commit yourself and your collaborators to specific confidentiality obligations

◯ To perform and publish a Data Protection Impact Assessment

◯ To provide a specific publicly visible privacy

◯ To check if special conditions are applicable, considering the private/public nature of your entity/ organisation

# Phase 1
## Research Proposal

### Data Protection

#### For all other data:

- ◯ Identify whether or not specific conditions and/or safeguards apply to your research according to your national legal framework and/or research area
- ◯ Identify whether or not there are any codes of conduct applicable for your data processing
- ◯ Identify specific means of data processing
- ◯ Identify the external governance of data processing
- ◯ Identify the internal governance of data processing
- ◯ Identify which data are necessary for each step of the research and define how you will pseudonymise personal data
- ◯ Identify where you are going to store your data
- ◯ Identify if other uses than the initial ones are envisaged, and therefore consent from the data subjects is needed
- ◯ Identify if you are compliant with the principle of minimisation and proportionality

#### If you are going to process personal and non-personal data through AI-based technologies or machine learning techniques, please make sure you

- ◯ Verify together with your ethics advisor (if appointed) or knowledgeable staff in your entity/organisation whether or not there are any conditions stated by the specific applicable ethical-legal framework both at EU and national level
- ◯ Address how you will be compliant with the pillars of ethics, lawful, and robust AI, namely
  - Explain how the developed/used AI technologies meet the criteria for trustworthiness;
  - Define the measures set in place to avoid potential bias, discrimination and stigmatisation;
  - Define the measures set in place to ensure safety and prevention of harms (to humans, animals, environment);
  - Prepare a detailed explanation on how the respect for fundamental human rights and freedoms (e.g. human autonomy, privacy and data protection) will be ensured;
  - Define measures to ensure fairness and explicability (paying particular attention to situations involving more vulnerable groups);
  - Explain how humans will maintain meaningful control over the most important aspects of the decision-making process (especially in those instances in which the AI systems/techniques to be developed/used may interact, replace or influence human decision-making processes);
  - Evaluate the ethics risks related to the development/deployment of the AI systems/techniques and explain how the potential negative social impacts will be mitigated (especially when the AI to be developed/used in the project may lead to significant social impacts either through intended applications or plausible alternative uses).

# Phase1
## Research Proposal

### Data Protection

**If you are going to process either personal or non-personal data extra-EU, make sure you**

- ◯ Check the conditions to share them
- ◯ Verify whether or not specific conditions apply for private/public institutions

**If you are required to submit a protocol to the competent ethical committee, make sure you**

- ◯ Allocate time and resources
- ◯ Identify the competent ethical committee
- ◯ Identify all the required documents and information

**In any case, if you are going to process non-personal data, make sure you**

- ◯ Allocate costs for data management
- ◯ Identify safety requirements to process data
- ◯ Identify proper format to facilitate their interoperability and the re-use
- ◯ Identify a proper repository

Next > Phase2

# Phase 2
## Research Implementation

Along with the conditions to be verified in the proposal phase, which must be monitored and updated also during the research implementation, the second phase requires compliance with additional requirements.

### Intellectual Property Rights (IPR)

#### Make sure to develop an IP management plan containing

◯ An innovation or creation disclosure mechanism, to facilitate identification or description of research outcomes eligible for IP protection

◯ Identification of the internal office in charge of assisting with patent applications and other registrations required to achieve IP protection

◯ IP acquisition principles and policies, including at least
- Decisions on territoriality (where to apply and why),
- Ownership matters, i.e. how to regulate cases of joint development and co-ownership,
- Clearance matters, i.e. how to deal with cases where access to external IPRs is necessary to protect your own intellectual capital.

◯ IP management matters, including at least
- Monitoring of fee payments and other maintenance issues,
- Cost-cutting measures if protection is not needed anymore,
- Clear public disclosure of IPRs, applicable legal regime and re-use conditions.

◯ IP exploitation processes, including at least
- The definition of common consortium policies and internal policies identifying the principles and goals to be pursued in exploitation activities E.g. balance between proprietary approach necessary to reach adoption/ commercial exploitation and OA/OS policies allowing free re-use (as open as possible, as closed as necessary)
- Definition of cases when to adopt cross-licensing agreements between partners (on background IPRs or IC developed jointly but attributed in single ownership), possibly on a non-exclusive and gratuitous basis.
- The selection of a set of licensing templates ranging from traditional commercial exploitation to open access and open science formats (e.g. Creative Commons, GNU/GPL or EUPL free non-exclusive patent licenses etc);
- The implementation of processes of periodic checks to allow the OA/OS dissemination of materials covered by embargos, once embargo periods expire.

◯ Put in place clearance processes and systems that identify IP flexibilities and leverage them to afford re-use of protected materials without requesting rights holders' authorisation

# Phase2
## Research Implementation

### Data Protection

If you process any information that identifies, directly or indirectly, a human person, please be aware to follow this checklist.

**If you have appointed staff, please engage the DPO, the ethics advisor or the ethical-legal unit to provide the compliance activities**

**If you are going to process either general or special categories of data, be aware to implement the technical and organisational measures required to protect your data flows in terms of availability, confidentiality, and integrity. Make sure you**

- ◯ Have filled in the records of the processing under article 30 GDPR
- ◯ Have assessed the impact under article 35 GDPR
- ◯ Have regulated the governance under articles 26 and/or 28 GDPR if third parties are involved in the processing (so-called external governance)
- ◯ Have informed data subjects
- ◯ Have received the approval of the competent ethical committee (if required)
- ◯ Have trained collaborators, instructed, and therefore authorised them under article 29 GDPR (so-called internal governance)
- ◯ Have obtained a commitment for confidentiality obligations (if required)
- ◯ Have established procedures to ensure data subjects exercise their rights
- ◯ Have established procedures for data breaching
- ◯ Have identified the proper technique of pseudonymisation
- ◯ Have identified how to encrypt your data
- ◯ Have planned stress tests to identify infrastructural vulnerabilities
- ◯ Have planned auditing activities

# Phase2
## Research Implementation

### Data Protection

#### A Data Management Plan (DMP) shall be provided and implemented

◯ A repository shall be chosen in order to collect research data, check the most common one used in your research community

◯ Create a general chart where you provide all the data curation information for each data flow

◯ Identify convergences and divergences in the described categories of research data

◯ Decide how you plan to make similar categories of research data as open as possible, as close as necessary

- The ethical-legal, IPRs, and commercial constraints shall be identified.
- Identify how you will describe your research data (findable).
- Identify how you will make your research data accessible.
- Identify which is the format that will make your data interoperable.
- Identify how your data could be re-usable.

◯ In the case of archive services, identify conditions to reverse pseudonymisation to not endanger the evidential value of the records (e.g. a procedure of requests by the researcher)

#### Any innovative feature (new data processing, new means, new purposes, new target groups) shall be re-assessed

#### If you are analysing data, verify the threshold of aggregation beyond which publication and dissemination of personal data is required.

Next > Phase3

# Phase3

## Research review

After the conclusion of a funded research project or any other form of a research undertaking, additional issues should be checked, and some of the processes should remain in place to ensure persisting compliance and the rolling implementation of FAIR principles and Open Access and Open Science policies.

### Intellectual Property Rights (IPR)

- ◯ **Identify, with your TTO or legal office, maintenance mechanisms to ensure that your IP management plan keeps on running and is subject to periodic checks also after the conclusion of the research project**

- ◯ **Maintain and update clearance processes and systems that identify IP flexibilities and leverage them to afford re-use of protected materials without requesting rights holders' authorisation**

- ◯ **Run periodic checks to allow the Open Access/Open Science dissemination of materials covered by embargos, once embargo periods expire**

- ◯ **Verify compliance with license agreements by your licensees, and particularly respect of FAIR, Open Access and Open Science clauses**

**Run compliance checks of your status on institutional repositories. Ask yourself**

- ◯ Have I uploaded all the materials (papers, background data, etc) which I can freely disseminate?
- ◯ Am I using interoperable and accessible formats?
- ◯ Have I provided the correct metadata?

**Help your institution be up-to-date with the state of the art in the implementation**

# Phase3
## Research review

**Data Protection**

- ◯ Determine how long you shall store informed consent from research subjects and act accordingly
- ◯ Remove any access to no longer authorised entities/bodies/collaborators shall be removed
- ◯ Check if you have pursued all the instructions you provided within the data management plan
- ◯ The re-use policy shall be clearly identified
- ◯ Proper retention location and access privileges for data whose further use is enabled should be identified and consequent actions adopted

## Thank you!

# Remember to save this document before closing it

# EOSC-Pillar

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