

White Paper 2: Data Protection, Assurance, Special Regimes and Property Rights

Supporting Document to D3.3 Draft Policy Recommendations

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SUMMARY: TOWARDS DRAFT POLICY RECOMMENDATIONS

Data protection differs from other constraints on open science in that its rules and regulations have the clearly-defined aim of protecting the fundamental rights and freedoms of data subjects. The General Data Protection Regulation (GDPR), the new binding EU regulation on data protection, sets novel standards for the protection of those rights and freedoms. With its implementation in individual member states still ongoing, its exact interpretation and its impact on open science remain unknown. It is, however, already clear that the EOsc needs to be in compliance with the GDPR, making it crucial to raise awareness among EOsc stakeholders on issues arising from the GDPR and recommendations on how to deal with these issues as well as their potential divergent member state implementations, both for current and for future stages of work in this subtask. For this reason, most of the recommendations provided in this paper, when considered on a continuum of legal and policy recommendations, fall closer to the legal end.

The main difficulty facing this subtask arises from the differing levels of harmonisation due to member states' use of the opening clauses in the GDPR. Our primary recommendation, then, is that the EOsc raise awareness regarding possible difficulties stemming from said use of opening clauses. This is relevant for both research projects between member states and for institutions individually.

Art. 89 GDPR remains the most crucial factor in identifying possible differences among member states with regard to the processing of personal data for scientific research purposes. It allows member states to derogate from certain rights granted under the Regulation (Art. 15, 16, 18, 21 GDPR) if the processing is for scientific purposes. Furthermore Art. 9 II (j) GDPR in conjunction with Art. 89 GDPR constitutes a legal ground for processing special categories of personal data. Given the scope of action granted to member states by Art. 89 GDPR, scientific data processing contexts and their regulation might be the area of GDPR implementation where harmonisation is most likely to be compromised.

Our recommendations are as follows:

First, the EOsc needs to set a framework for data processing based on the consent of the data subject as stated in Art. 6 I (a) GDPR Art. 9 II (a) GDPR. The concept of consent raises questions regarding the reuse of data. The purpose of any data recording and processing must therefore be explicitly defined. Regarding the difficulties of adopting a definite research purpose, recital 33 GDPR states that data subjects should be allowed to give their consent to certain areas of scientific research when in keeping with relevant recognised ethical standards. As Art. 7 III GDPR grants every data subject the right to withdraw consent at any time, we recommend the EOsc include a system that ensures data subjects are able to do so.

As a second step the EOsc should monitor how different member-state data protection legislation may affect scientific research, including the identification of the available room for harmonisation in the context of said legislation. In this manner, policies developed by the EOsc will be well equipped to give guidance on the gradual set-up of a European research platform with special and harmonised data protection rules. This task could be performed by the EOsc itself as a function of governance or by research infrastructure providers.

Following this, the EOsc's paramount objective should be defining the particular legal bases for data processing and providing specific guidance on specific requirements. As approximately half the member states have not yet finished the implementation process, this remains a task for the future.

The next sensible step would be, taking on a user-oriented point of view, with the EOsc adopting policies that help identify personal data and special categories thereof. The EOsc could classify participants according to how and what kind of data is being processed by means of "special regimes". We recommend research infrastructure providers include a tagging system that at a bare minimum differentiates between personal and non-personal data and special categories of the former (which some EOscpilot stakeholders have already implemented).

Next, the EOsc should seriously consider developing policies on the particular implementation and effective enforcement of those data subject rights within the EOsc where no member state derogation is foreseen by the implementation of the GDPR. For such policies to be effective, a sensible idea would be to provide data

subjects (including data donors and users) with adequate guidance on their rights and obligations regarding scientific data processing, illustrated by application tools. Users should be made familiar with the relevant provisions of the GDPR. Training should also be offered to staff at research infrastructures and research-providing organisations.

Finally, on a more technical level, the EOsc could implement time-limited access and technical protocols. These could be combined in a personalised policy catalogue for each user, which would also work as an assurance of compliance with data protection laws. Users could formally declare how their personal data will be processed and receive information about relevant changes (e.g. in data protection rules related to special regimes). As a result, the EOsc would be equipped to adapt smoothly to legal changes and various regulatory approaches while also meeting its documentation obligation.

These draft recommendations will be validated in the next phase of work through wide consultation, including with the Science Demonstrators which are still ongoing, and so may provide new input as a result of their continuing experience.

1. METHODOLOGY AND FUNDAMENTALS

These proposals for the development of EOsc policies regarding data protection, intellectual property rights, special regimes and assurance were jointly developed and refined in the weekly virtual meetings of subtask 3.1. We have paid particular attention to the EOsc's data processing needs as explained by our scientific demonstrators and, within that context, to specific policy needs for the processing of special categories of personal data. We have categorised scientific demonstrators according to the kind of data they deal with (geodata, public data, confidential data, special categories of personal data, e.g. health-relevant data, other scientific demonstrators) and while some may not be significantly affected by data protection regulations, their valuable contributions have granted us an overview into the issues and allowed us to identify data protection as the key issue for this subtask. We have established close cooperation between the two subtasks of data protection (3.1.2) and ethics (3.1.4).

Given the clear importance of data protection for this subtask, it became clear that further aspects of IPR, special regimes and assurance should be considered at this stage only insofar as they influence the development of data protection policies. This naturally leads to the GDPR becoming a central focus point. In order to identify existing relevant rules in the context of data protection, a micro policy landscape has been established based on the previous D3.1 deliverable. Nevertheless, crystallisation of concrete policy for the EOsc is still fundamentally influenced by member state implementations of the GDPR, and the Science Demonstrators are also currently still ongoing. Thus, extensive comparative policy work still lies ahead for the EOsc, although valuable input (including but not limited to the questions from experts included below) has been provided. We have developed a questionnaire in order to accommodate expert contributions at this early phase and to set the stage for representative feedback to progress work in the required direction.

2. TOWARDS DRAFT POLICY RECOMMENDATIONS IN DETAIL

2.1. Drivers and Constraints: Initial Scope and Focus

The mission of EOSCPilot subtask 3.1.2 was the exploration of different types of regulatory regimes for research and scientific data, in particular data protection, intellectual property rights, special regimes and assurance.

As research data is¹ increasingly collected by multiple sources, both the availability of such data and the constraints on its use play a crucial role in how it could be further reused. An evaluation of the necessity of a controlled data access approach under various regulatory regimes has also been proposed. Property regimes can add both to the restriction of data flows and to the facilitation of data release, if they are openly licensed or fall under a public domain regime. In this context, licensing strategies play a crucial role at both the acquisition (with regard to the process of in-licensing) and data release stage.

However, data protection was not chosen as the focus of 3.1.2 solely in order to explore its regime in terms of regulatory compliance, but also in terms of managing consent and its revocation, and practices for the use of privacy-enhancing technologies, systems and techniques. We have paid particular attention to data inheritance, traceability, and provenance, aiming at improving reproducibility aspects of research as well as supporting processes related to special categories of personal data.²

Finally, we explored the role of security frameworks, security transfers and strengthening cybersecurity against intrusions.³

2.2. Information Sources: Micro Landscape Review, Policy Workshops

2.2.1. Existing Policies With Relevance for EOSC⁴

Data Protection Policies:

- Reform of EU data protection rules, http://ec.europa.eu/justice/data-protection/reform/index_en.htm
- 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), <http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32016R0679&from=EN>
- DIRECTIVE (EU) 2016/680 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 27 April 2016 on the protection of natural persons with regard to the processing of personal data by competent authorities for the purposes of the prevention, investigation, detection or prosecution of criminal offences or the execution of criminal penalties, and on the free movement of such data, and repealing Council Framework Decision 2008/977/JHA, <http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32016L0680&from=EN>
- Proposal for a Regulation on Privacy and Electronic Communications, <https://ec.europa.eu/digital-single-market/en/news/proposal-regulation-privacy-and-electronic-communications>

IPR relevant documents (general level):

¹ Cf. <http://understandingpatientdata.org.uk/what-are-best-words-use-when-talking-about-data>

² Terminology of the GDPR, cf. D3.3. glossary p. 57.

³ EOSCpilot WP3 DoW.

⁴ EOSCpilot D3.1 Policy Landscape Review, document is available here: <https://eoscipilot.eu/sites/default/files/eoscipilot-d3.1.pdf>; the list of policies is not exhaustive, but contains the most relevant documents.

- COM(2017) 707 - A balanced IP enforcement system responding to today's societal challenges, <https://ec.europa.eu/docsroom/documents/26581>
- COM(2017) 708 - Guidance on certain aspects of Directive 2004/48/EC of the European Parliament and of the Council on the enforcement of intellectual property rights, <https://ec.europa.eu/docsroom/documents/26582>

Copyright Policies:

- EUIPO 2017 work programme, https://euipo.europa.eu/tunnel-web/secure/webdav/guest/document_library/contentPdfs/about_euipo/the_office/work_programmes/Work_Programme_2017_en.pdf
- EUIPO 2016 annual report, https://euipo.europa.eu/tunnel-web/secure/webdav/guest/document_library/contentPdfs/about_euipo/annual_report/Obs_Annual_Report_2016_en.pdf
- IPR DG MARKT landing page, https://ec.europa.eu/growth/industry/intellectual-property_en
- Communication, 'A single market for intellectual property rights: Boosting creativity and innovation to provide economic growth, high quality jobs and first class products and services in Europe', <http://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:52011DC0287&from=EN>

Trade Secrets Policies:

- Trade Secrets Directive, https://ec.europa.eu/growth/industry/intellectual-property/trade-secrets_en

Patent Policies:

- Patent protection in the EU: EC patents landing page, https://ec.europa.eu/growth/industry/intellectual-property/patents_en
- COMMISSION STAFF WORKING DOCUMENT Towards enhanced patent valorisation for growth and jobs, <http://ec.europa.eu/DocsRoom/documents/9963/attachments/1/translations>
- COMMUNICATION FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT, THE COUNCIL, THE EUROPEAN ECONOMIC AND SOCIAL COMMITTEE AND THE COMMITTEE OF THE REGIONS Europe 2020 Flagship Initiative Innovation Union SEC(2010) 1161, https://ec.europa.eu/research/innovation-union/pdf/innovation-union-communication_en.pdf
- The Unitary Patent System (landing page), https://ec.europa.eu/growth/industry/intellectual-property/patents/unitary-patent_en
- Regulation (EU) No 1257/2012 of the European Parliament and of the Council of 17 December 2012 implementing enhanced cooperation in the area of the creation of unitary patent protection, <http://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:32012R1257&from=EN>
- COUNCIL REGULATION (EU) No 1260/2012 of 17 December 2012 implementing enhanced cooperation in the area of the creation of unitary patent protection with regard to the applicable translation arrangements, <http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32012R1260&from=EN>
- NOTICES FROM EUROPEAN UNION INSTITUTIONS, BODIES, OFFICES AND AGENCIES COUNCIL AGREEMENT on a Unified Patent Court, [http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:42013A0620\(01\)&from=EN](http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:42013A0620(01)&from=EN)

2.2.2. Main Scientific Demonstrators

Geodata:

- ENVRI/ERFI⁵: The “ENVRI Radiative Forcing Integration” science demonstrator focuses on the integration of data/services between the “edges” of Environmental Research Infrastructures

Public data:

- SHARE-PSI⁶ offers advice on implementation the PSI directive and therewith the availability of public information
- LAPSI⁷ (Legal Aspects of Public Sector Information)/LAPSI2 is a research project promoted and deals with the legal problems regarding Public Sector Information.

Confidential data:

- ADOPT BBMRI-ERIC⁸ establishes, operates and develops a pan-European distributed research infrastructure of biobanks and biomolecular resources

Special categories of personal data, such as health data:

- PCAWG⁹ is an international collaboration to identify common patterns of mutation in more than 2,800 cancer whole genomes from the International Cancer Genome Consortium. The project produced large amounts of special categories of personal data.

Further scientific demonstrators:

- CLARIN¹⁰, language data infrastructure for research especially in social sciences and humanities
- DARIAH¹¹ data and infrastructure for research in the humanities and cultural sciences
- and META-NET¹² language technology and multilingual data centres
- EnCoRE¹³ promotes research and education in the field of conservation-restoration of cultural heritage
- and Europeana¹⁴ provides access to over 50 million digitised items – books, music, artworks and more
- Generic Research Data Infrastructure (GeRDI)¹⁵: Frictionless data exchange across research data, software and scientific paper repositories.

2.3. Policy Issues Shortlisting

Subtask 3.1.2 has so far identified a number of key policy issues. EOSCpilot aims to enable the participating research institutions to efficiently work together, thus enabling open science. This requires that research data be exchanged as freely as possible between the researchers and institutes involved. On the other hand, personal data, in particular special categories of personal data and data protected by intellectual property rights, must receive legal protection and the legal requirements for the processing and transfer of such data must be complied with.¹⁶ The various clashing legal positions of actors involved in specific data processing

⁵ <https://eoscipilot.eu/science-demos/envri-radiative-forcing-integration>

⁶ <https://www.w3.org/2013/share-psi/>

⁷ <https://nexa.polito.it/lapsi2>

⁸ <http://www.bbmri-eric.eu/scientific-collaboration/adopt-bbmri-eric/>

⁹ <http://docs.icgc.org/pcawg/>

¹⁰ <https://www.clarin.eu/>

¹¹ <https://www.dariah.eu/>

¹² <http://www.meta-net.eu/>

¹³ <http://www.encore-edu.org/>

¹⁴ <https://www.europeana.eu/portal/de>

¹⁵ <http://www.gerdi-project.de/>

¹⁶ EOSCpilot D3.1 Policy Landscape Review, p. 80, document is available here: <https://eoscipilot.eu/sites/default/files/eoscipilot-d3.1.pdf>;

via cloud-based data activities still need to be reconciled via policy guidance. The establishment of such a regulatory framework should create a system that is clear and user-friendly for all parties.

The partial incoherence of the relevant legislation must also be addressed. The harmonisation level of data protection (or intellectual property) rights is not very high.¹⁷ EU member states have the power to derogate from certain rights codified in the GDPR or enact laws regarding specific data processing situations. Although there are many legitimate reasons to enable member states to enact their own regulatory regimes, this situation makes it difficult for the EOsc to bring researchers, industries and private individuals together on a single cloud platform and make sure they are able to conduct open science. The GDPR's various opening clauses present a particular challenge when dealing with data protection law. These clauses permit member states to derogate from the provisions of certain articles of the GDPR. There also exists no uniform EU-wide regulation for intellectual property legislation. The EOsc must find policy, governance and management solutions to these problems.

With respect to assurance, privacy by default and privacy by design are important approaches to implementing and reaching compliance with EOsc policies. Moreover, data quality and security measures will be of ever-increasing significance. Researchers are expected to adhere to and promote high standards for their scientific endeavours and the quality of data they process.

Gauthier Chassang, The impact of the EU general data protection regulation on scientific research, in: *Ecancelmedicalscience*. 2017; 11: 709; Published online 2017 Jan 3. doi: 10.3332/ecancer.2017.709, PMID: 28144283.

¹⁷ Particularly concerning IPR-related legislation, the law-making process did not make sufficient progress in the last years, compare only: https://ec.europa.eu/growth/industry/intellectual-property/patents_de.

3. INITIAL DRAFT POLICY RECOMMENDATIONS

Any regulation regarding data protection in the EOsc must be in line with the legally binding requirements of EU law, and this is true equally for the GDPR which as discussed above is the particular focus of this paper.

3.1. Data Protection Regulations, With Particular Focus on the GDPR (meta level)

The GDPR is the most important data protection legislation at the EU level. However, despite its directly binding nature¹⁸, the level of harmonisation across the EU is not consistent, due to the aforementioned opening clauses allowing member states leeway in adopting national regulations.

3.1.1. Opening Clauses

The opening clauses in the GDPR take account of the different legal foundations influencing data protection in different member states.¹⁹ They also promote loyal cooperation between the EU and member states and take account of the subsidiarity principle codified in primary EU law, while making room for the principles of limited EU authorisation and proportionality.²⁰

Opening clauses could be categorised in many different ways – as optional opening clauses and compulsory completion obligations, for example. They can also be divided up according to their application – some apply generally (i.e. they are not limited to a specific subject area, see Art. 23, 85 GDPR), where others are sector-specific (see Art. 8 GDPR, which regulates the consent of minors to the use of information society services). Finally, there are the options member states have for dealing with the clauses – some opening clauses entitle them to make additions, others to specify or modify the Regulation.

Some opening clauses such as Art. 89 GDPR are used relatively extensively and will thus play a crucial role in national legislation and inevitably influence the EOsc. Other opening clauses have been used less frequently by member states or have no relevance to the EOsc. For example, the EOsc has little need to adopt any policies on supervisory authorities and their ability to impose sanctions and fines.

We must therefore first analyse the existing opening clauses and their relevance to the EOsc, and then determine how an EOsc policy could implement the obligations, and the scope of discretion. Where member states have made use of opening clauses, they enact binding legal provisions which must be observed by those falling within the particular jurisdiction.

Once the overall picture is clear, the EOsc could simply take the most restrictive regulation as a standard. This would have the advantage of keeping standards relatively uniform, assuming it is not *too* restrictive – in that case, using multiple regimes would be the sensible option.

The EOsc is not entitled to make use of the leeway granted to member states. The EOsc must observe binding EU law, which means the GDPR as it is. This must not, however, hinder the EOsc from getting involved with policymakers and encouraging harmonisation.

Opening clauses which allow member states to restrict rights or reduce protection would have to be examined to see whether they are implemented in a mandatory manner. If this is not the case, a uniformly

¹⁸ Paul de Hert, Vagelis Papakonstantinou, The new General Data Protection Regulation: Still a sound system for the protection of individuals? Computer law & security review 32 (2016) 179–194, available at: https://ac.els-cdn.com/S0267364916300346/1-s2.0-S0267364916300346-main.pdf?_tid=8befb4aa-8d95-4644-9af7-91fcd7fdc4fd&acdnat=1523440358_b5d75862fb87a40a3378e8f478e82fee.

¹⁹ Baker/McKenzie provide an overview on the EU-member state legislation concerning the law-making process with respect to the opening clauses of the GDPR, https://www.bakermckenzie.com/-/media/files/insight/publications/2017/06/bk_itc_gdprsurvey_2017.pdf?la=en.

²⁰ Wagner, J; Benecke, A, National Legislation within the Framework of the GDPR, European Data Protection Law Review, p. 353, 2016.

high standard of protection could be agreed on for the EOsc, ignoring member states' implementation of these clauses. However, individual adherence to such a standard might be problematic.

3.1.1.1 General Processing Requirements

Opening clauses concerning the general requirements of personal data processing can be found in articles 4, 6, and 7 GDPR, and these requirements raise questions for the EOsc. The concept of “consent” as defined in Art. 4 GDPR, for example, raises certain challenges regarding the reuse of data for scientific research. It will also be difficult to pursue programmes in compliance with the GDPR if their scientific purposes are not clearly defined from the very beginning. Articles 6 and 7 GDPR are of particular relevance for the EOsc since they contain the legal bases for data processing and allow member states to specify legal requirements under certain conditions.

Given that research-providing institutions, as part of the EOsc user group, will process data that in many circumstances is personal or belongs to a special category, the legal requirements for their processing are of crucial relevance for the EOsc and will need to be carefully observed going forward. However, specific national legislation will only be applicable to those EOsc users who fall within its national jurisdiction, which would be determined based on various factors such as controller identity or user location; for all others – on the member state level – it will be irrelevant. It is therefore vital that the EOsc comes to a decision on how to deal with different member state regulations.

3.1.1.2 Controller and Processor

Further opening clauses setting out processing requirements can be found in Articles 26, 28, 29, 32, 35-37 and 43 GDPR. These regulations²¹ are also of enormous importance for the EOsc, because they concern the duties of the controller and the processor. These include supervisory duties and control mechanisms as well as the reporting of breaches of duty to supervisory authorities and any persons concerned. This section also contains regulations on data protection officers. As the EOsc aims to enable various actors to process personal data, it needs clear structures and policies in order to inform those responsible of their respective rights and obligations. We expect difficulties to arise here where the member states have made use of opening clauses e.g. in the case of integrated and well-structured user interfaces. The regulations in this part of the GDPR cover interaction between EOsc users and workflow functionality. Researchers from different EU member states working together, with some acting as processors and some as controllers, could be faced with legal obstacles – joint projects hindered by incompatible legal obligations, for example – which could qualify as constraints on harmonised EOsc policies. The EOsc cannot hinder member states from making use of the opening clauses, but it can proactively raise awareness of said difficulties and encourage harmonisation.

3.1.1.3 Research and Science, Statistics and Historical and Statistical Processing

Art. 89 GDPR also contains an opening clause and regulates guarantees and exceptions for the processing of personal data for scientific or historical research purposes, statistical purposes and archiving purposes in the public interest. It is of great importance for EOscpilot since scientific research will be the central reason for the establishment and maintenance of the EOsc. Furthermore, the exemptions laid down in Art. 89 GDPR leave wide room for discretion. It follows that member states' usage of this provision and the resulting level of harmonisation is of vital importance and will shape EOsc policy. Another critical aspect of relevance to the EOsc's functionality is that constraints on scientific research are not limited to incompatible regulations making scientific cooperation difficult: we must also keep in mind the general aim to share findings, generate

²¹ Paul de Hert, Vagelis Papakonstantinou, The new General Data Protection Regulation: Still a sound system for the protection of individuals?, computer law & security review 32 (2016) 179–194, available at: https://ac.els-cdn.com/S0267364916300346/1-s2.0-S0267364916300346-main.pdf?_tid=8befb4aa-8d95-4644-9af7-91fcd7fd4fd&acdnat=1523440358_b5d75862fb87a40a3378e8f478e82fee .

value for all participants and exercise open science. Where member states lower restrictions on research-conducting institutions processing personal data, they increase scientific outcomes. More innovation also means more commercial output, so the EOsc must create a solution that fits best for all, especially to prevent a race to the bottom. Nevertheless, leeway for member state regulation can be necessary for the same reasons mentioned above regarding opening clauses, which means the specific level of harmonisation necessary for the EOsc to function still needs to be clarified.

3.1.1.4 Freedom of Expression, Freedom of Information

Art. 85 GDPR concerns the relationship between the protection of personal data and freedom of opinion and information and also allows member states to make derogations. Freedom of opinion and information is closely related to scientific freedom and therefore of relevance for the EOsc. The EOsc stands for an open science society: different research-conducting institutions coming together as a team, seeking innovation. Nevertheless, these freedoms can be restricted because of other, equally relevant rights (e.g. individual rights related to data protection). The EOsc should be capable of balancing these adverse legal interests, so we expect it to have significant influence on member states regarding the enactment of regulations when the potential obstacles posed by clashing legal positions are explained clearly and appropriate awareness is raised.

3.1.1.5 Transfers of Personal Data to Third Countries and International Organisations

Another opening clause in Art. 49 GDPR covers GDPR provisions concerning the transfer of personal data to third countries and international organisations. This is of relevance to EOscpilot as some of the participating research institutes have the legal status of international organisations and also the EOsc intends to involve industrial partners which may be situated outside the EU.

Art. 49 GDPR concerns the exceptional admissibility of transfers where no other legal basis is available. Since it is therefore a fallback legal basis, it should be possible to rely primarily on one of the other legal opportunities given by the GDPR for data transfer. As only Art. 49 GDPR leaves room for discretion, the level of harmonisation should be quite high.

With respect to EOsc policymaking concerning transfers to third countries or international organisations, this presents an opportunity to treat the relevant parts of the regulation as per se binding law, according to which the EOsc could internally decide to consistently accept data transfers based on Art. 49 GDPR, should the conditions for transfers defined in the relevant articles be fulfilled.

3.1.1.6 Legal Protection and the Rights of the Data Subjects

Regulations which foster trust and lawfulness help drive open science.²² If data subjects are entitled to lodge complaints because their rights are infringed upon, it will help to create an environment of trust. As this is a necessary requirement for the functionality of the EOsc, the relevant provisions are important.²³

The GDPR contains many opening clauses concerning legal protection and the rights of data subjects. These can be found in Art. 14, 17, 23, 80 and 89 GDPR. These clauses partly enable member states to set derogations from these subjective rights – we have already covered how Article 89 in particular allows derogation in relation to scientific research (see 3.1.3). While this reduces the legal restrictions on the data controller and processor, it also reduces the data subject's level of protection. This can have negative consequences, especially when laws enacted across member states vary, lowering the harmonisation level. With this in

²² Additional aspects on the protection of individuals in the context of processing personal health-related data for insurance purposes, including data resulting from genetic tests can be found in a recommendation of the council of Europe, available at: https://search.coe.int/cm/Pages/result_details.aspx?ObjectId=09000016806b2c5f.

²³ Paul de Hert, Vagelis Papakonstantinou, The new General Data Protection Regulation: Still a sound system for the protection of individuals?, computer law & security review 32 (2016) 179–194, available at: https://ac.els-cdn.com/S0267364916300346/1-s2.0-S0267364916300346-main.pdf?_tid=8befb4aa-8d95-4644-9af7-91fcd7fdc4fd&acdnat=1523440358_b5d75862fb87a40a3378e8f478e82fee.

mind, it is necessary to precisely analyse the scope of member states' discretion and their implementation of the GDPR.

As noted above, the EOSC is not entitled to make use of the opening clauses. EOSC policies can therefore only react to EU legislation, and national legislation applies only to those who fall within its jurisdiction. We therefore recommend raising awareness of the need for harmonisation with respect to the EOSC and in the interest of supporting open science, innovation and market growth. EOSC policymakers should change from a reactive role to proactively using the EOSC platform to raise harmonisation levels and thereby the effectiveness of the EOSC. If responsible member state institutions know about the consequences of highly divergent national legislation, they might be willing to foster EOSC functionality. Step-by-step, differences could be reduced. While it might initially be useful for member states to make use of their leeway due to their different legal backgrounds on data protection, they may at some point be persuaded to adapt to a harmonised legal framework which could primarily rely on EOSC policies for research.

3.1.2. GDPR Regulations Lacking the Possibility of Derogation Based on EU or Member State Law

It is also necessary to analyse the implementation of those parts of the GDPR lacking opening clauses. What is the right method in this case? Is it necessary to specify the given obligations with respect to the EOSC? What binding character could such a specification have? Should specifications be implemented as guidelines or in the form of a code of conduct?

The non-variable regulations of the GDPR apply to all parties to the same extent. There are therefore no national regulations that differ from the EU regulation and the level of harmonisation is high, allowing EOSC policies to be uniformly designed.

On the one hand, there is the possibility of keeping EOSC regulation limited and merely referring to the current EU legal acts, i.e. primarily to the General Data Protection Regulation. This would have the advantage of being a fast, simple policy-making method, especially as ECJ case law (among others) applies to the EOSC just as it does to the rest of the EU.

On the other hand, this approach is not particularly user-friendly. Researchers, industry representatives and private individuals often have no legal background and knowledge. For their benefit, it would help to have the binding EU targets formulated specifically for the EOSC, or at least explained in a comprehensive manner. We are not, however, proposing a standalone explanatory text, but instead the presentation and clarification of concrete application examples – with the help of the competent data protection officers (Art. 37 (5) GDPR). This would aid understanding of the legal texts and may very well make EOSC users more willing to implement and comply with them.

Of course, the EOSC has certain special characteristics that influence the application of the regulation, and research-related differences in regulations will probably play a major role as well. It makes sense, then, to enumerate and explain the special features of the EOSC, so users can better understand their obligations and entitlements.

3.1.3. Codes of Conduct

The EOSC is conceptualised as a federation, a final layer on top of the various research networks. Right now, specialised researchers operate under many different codes, which raises the question of whether the EOSC should develop its own code of conduct for the processing of personal data, or at least get involved in the development of codes of conduct in key research areas. From the interview conducted with Heiko Tjalsma in advance of this paper, it seems that there is potential for a European Code of Conduct, which EOSC could contribute to – although it remains to be seen what such a code would entail, and how the EOSC could draw upon prospective codes of conduct such as the BBMRI-ERIC's health research code in its creation.

This reinforces the need to raise awareness of the EOsc, and to position it as a pioneer. From that position, EOsc policies can ensure uniform application of the Regulation, while simultaneously promoting open science throughout the EU and strengthening Europe's position on innovation.

3.2. Special Regimes

What are special regimes? The relevant EU-EOsc documents do not define this term, instead only giving examples (Public Sector Information, Geodata,²⁴ Statistical Data²⁵).

Let us take the EOsc as an example: Researchers from many different disciplines will be processing and sharing data on the EOsc platform. It might therefore be useful to classify the participants according to what data they will process and how they will process it. Health research certainly processes different data than the social sciences, for example. Special regimes could therefore be understood as the different disciplines of the participating research institutions. There are certain areas that are more strictly regulated than others, e.g. health research, others simply have different regulations. It is not, however, that simple – such subdivisions must be viewed critically, as they can never be unambiguous and will also never succeed in doing justice to all disciplines involved. Problems would arise if certain legal provisions had to be assigned – to whom does which regulation apply?

Alternatively, one could also differentiate according to what category of data is processed (public data, personal data, intellectual property data). This distinction is, however, already prescribed by law and therefore already exists, and as such adds no value for the EOsc, either.

The definition of special regimes thus raises difficult questions. One possible solution would be the creation of scenarios that provide rules for certain clear cases. These use cases could serve as a guide without, however, making a clear and binding classification.

To take one example, traditionally, personal and special categories of personal data are processed in health research. These research groups should therefore receive recommendations on respecting data protection laws. For literary studies that do not regularly work with personal data, however, data protection would be of secondary importance and so no recommendations are likely to be required.

It is however important to note that the EOsc's stated aim to foster research across diverse disciplines might reduce the benefit of special regimes divided by scientific research field.

Furthermore, the GDPR contains several provisions which only apply to certain processing situations. These include the processing of special categories of personal data (Art. 9 GDPR), data of underage data subjects (Art. 8 GDPR), processing in the context of employment (Art. 88 GDPR) and public-sector data processing (Art. 86 GDPR). In this context it might also be useful to categorise the GDPR regulations in order to enable researchers in the EOsc to easily identify provisions they must adhere to.

This could be done by introducing an identifier for sensitive data that can only be processed under certain conditions. The idea of tagging sensitive data also arose in our interviews with experts and is already performed by some of the EOsc's research infrastructures. We recommend splitting data into at least three categories: personal data, special categories of personal data and data that requires special conditions for processing (e.g. minor data subjects). Sensitive data could be pseudonymised, anonymised or encrypted to further enhance data protection (a note on pseudonymisation – it is important to mention that it itself constitutes “processing data” according to Art. 4 II GDPR and that the requirements of lawful processing thus also need to be fulfilled when pseudonymising data).

²⁴ EOscpilot D3.1 Policy Landscape Review, p. 60, the document is available here: <https://eoscpilot.eu/sites/default/files/eoscpilot-d3.1.pdf>.

²⁵ EOscpilot D3.1 Policy Landscape Review, p. 63, the document is available here: <https://eoscpilot.eu/sites/default/files/eoscpilot-d3.1.pdf>.

The same applies to IPR. IP laws differentiate by the type of intellectual property involved, which brings different legal rights and obligations into the picture. Certain disciplines may come into contact with IPR more often than others, and some may only come into contact with one specific kind of intellectual property.

In any case, there is no guarantee that any categorisation by discipline and intellectual property will be final. Furthermore, a distinction by intellectual property type is already prescribed by law, and thus already exists. Regarding IPR, it may also be useful to know whether certain situations are regulated specifically, as exceptional circumstances require a specific approach. We recommend building scenarios as guiding examples, to help determine which law applies.

3.3. Assurance

It is vital that the question of how best to implement the GDPR and EU IPR regulations for the EOsc and how assurance will be guaranteed be answered satisfactorily.

We recommend that the different actors in the EOsc be distinctly attributable to different user groups. Additionally, there should be a breakdown clarifying the function or capacity in which data is being processed. If personal data falling under the scope of the GDPR is being processed, there must be clarity as to who is the respective data subject, controller or processor, et cetera, as this categorisation is important for their respective rights and obligations.

For data whose processing is restricted due to IPR regulations, categorisation should be based on the level of protection of said data. In this case, it might make sense to classify the data not according to its sensitivity and the type of EOsc actor, but according to the way in which the data is processed and used. A further requirement would be the identification of the person responsible for the processing, the scope of the intellectual property and the person to whom the intellectual property belongs. A list could then be drawn up that assigns rights and obligations to the respective groups and processing methods. This could simply be the application of GDPR and respective IPR legislation standards, or a more elaborate representation of the EOsc context.

An additional layer of classification would be the type of data processed. This would have the advantage of making it easier to identify and implement special rules that only affect certain areas. For example, data could be sorted by the level of protection needed, or by the topic (special regimes).

One option would be to create a precedent-setting digital policy catalogue. Such a catalogue might work in a personalised fashion: A user would log in with their special profile and declare formally how they will be processing personal and IPR-protected data, whereupon the policy catalogue would reply with individually applicable policy rights and obligations. This catalogue could then be revised regularly, with non-binding guidelines and recommendations being added step by step according to the specific kind of processing and the profile of the user, who could be immediately informed of any changes in rights or obligations.

Furthermore, by tagging actors, processing types and policies, the regulation could keep pace with automated processing and assurance will be guaranteed, as any data processing not explicitly legally permitted would be automatically forbidden. We suggest, for example, time-limited access in order to guarantee the observance of data protection obligations, along with technical protocols for any processing of personal data. The ways in which processing would be permitted could then be adapted to the special needs of EOsc users – a process which would allow the regime to become more detailed and extensive, step by step. Moving past the legal aspects of assurance, we come to another crucial point: quality and security assurance methods. The research conducted in the EOsc is meant to be of the highest standard and should have great potential for innovation and strengthen the EU's leading role in the world. The EOsc therefore has to make sure that research quality remains high, that no data is misused and that all participating

organisations have the necessary education in terms of scientific research and the technical knowhow in order to truly make use of the EOsc’s potential.²⁶

The EOsc should supply guidelines and recommendations for the education required. It might also be possible to provide training material, concerning, for example, the technical setup of the EOsc and its functions, or the quality of data processed on the EOsc platform. The EOsc could also offer courses which could, in the case of data management skills for example, also cover legal information.

3.4. Data Protection Officer

Another aspect of assurance is the question of whether EOscpilot needs its own data protection officer. Each of the participating organisations and research-conducting institutions have an obligation at the institutional level to employ a data protection officer, who can make sure the data protection regulation is correctly implemented. The question is whether coordination on the EOsc level would be fruitful. Situations may occur in which the data protection officer on the institutional level is overburdened. However, whether the EOsc itself will be processing personal data on a large scale, whether it will be obliged to designate a data protection officer under member state law complementing the GDPR or which legal form if at all it will have are all still open questions, which make it impossible to determine whether the EOsc could or should appoint its own DPO. If the EOsc does not do so, it is still worth considering establishing a single point of contact for data subjects involved in the EOsc. This could enhance data subjects’ trust in the EOsc and have positive effects on their willingness to support the EOsc and scientific research in general.

²⁶ The European Research Area develops policies supporting open science related skills and data related skills, http://ec.europa.eu/research/era/index_en.htm.

4. CONCLUSIONS

In light of the above considerations, it seems advisable to follow a number of steps in the following months. Firstly, there should be a regular examination of member state implementation of national law re the GDPR; and how this is relevant to the EOsc. Secondly, efforts should be taken to determine which legal bases are likely to apply to EOscpilot data processing, before focusing on the particular requirements for processing on the specific lawful basis. Thirdly, policies should provide controllers and processors with concrete advice, particularly about methods for adhering to the data processing obligations and requirements laid down in Articles 24, 26 and 28 GDPR, specifically regarding the setup and functioning of the EOsc. In particular, EOsc policies should include recommendations on how (joint or dual) controller and processor responsibilities might be dealt with in large multinational projects.

Many questions related to data protection issues are connected to the as yet unclarified legal status of the EOsc itself. Once this is clarified it will be possible to make more precise recommendations including, for example, in the matter of a potential EOsc data protection officer. The Science Demonstrators are also still ongoing and may provide further input which shapes the recommendations, based on their experience.

Moreover, Art. 89 GDPR remains a most crucial provision in identifying possible differences among member states with regard to processing of personal data for scientific research, as this norm applies when relying on the research exemption in Art. 9 2 (j) GDPR, as well as providing member states with their ability to derogate from the rights granted under the GDPR where processing is for scientific research – this might very well be where harmonisation will be compromised. Altogether, Art. 89 GDPR demands significant attention. From this follows the need to further discuss Arts. 6 1 (a), (e) and (f) as well as Art. 9 2 (j) GDPR, as well as Art. 89 (1) safeguards and Art. 89 (2) derogations are to be taken into account. It is right here that harmonisation issues might be exposed.

5. IMPLICATIONS OF RECOMMENDATIONS FOR STAKEHOLDERS

The table presented on the following pages summarises possible implications of the recommendations for each of four key stakeholder groups

- EOsc Governance structures and the Rules of Participation
- Funders and Ministries
- Research Producing Organisations
- Research Infrastructures

Some of these implications are requirements – because some stakeholders will be involved in funding and organising the recommendations, others are impacts, and describe the beneficial consequences of implementing the recommendations.

Draft Policy Recommendation	EOsc Governance/Rules of Participation	Funders and Ministries	Research Producing Organisations	Research Infrastructures
<p>DP1. Legal basis for data protection: consent and legitimate interest of controller. For data processed through the EOsc:</p> <p>i) Define explicit purpose of all data recording and processing</p> <p>ii) Apply a concept of tiered consent (in compliance with “broad consent” of the GDPR)</p> <p>iii) Adapt privacy-by-design and privacy-by-default solutions (providing data subjects with a technological solution for consent withdrawal)</p>	<p>(a) Implication: EOsc governance should include a management system for personal data related to data recording and processing purposes.</p> <p>(b) Impact: essential to meet the requirements of the GDPR.</p> <p>(c) Impact: high, uniform, standard of data protection for the EOsc.</p>	<p>(d) Implication: funding of relevant actions by EOsc, RPOs and RIs.</p> <p>(e) Impact: essential to meet the requirements of the GDPR.</p> <p>(f) Impact: high, uniform, standard of data protection for the EOsc.</p>	<p>(g) Implication: tiered consent</p> <p>Careful documentation of consent to particular research areas.</p> <p>(h) Impact: essential to meet the requirements of the GDPR.</p>	<p>(i) Implication: RIs need to provide (and if necessary develop) privacy-by-design/privacy-by-default systems and processes.</p> <p>(j) Impact: essential to meet the requirements of the GDPR.</p>

Draft Policy Recommendation	EOSC Governance/Rules of Participation	Funders and Ministries	Research Producing Organisations	Research Infrastructures
<p>DP2. Opening clause of Art. 89 GDPR</p> <p>i) The EOSC should constantly monitor EU and member state legislation to</p> <ul style="list-style-type: none"> - examine relevant changes in said legislation influencing data processing; - raise awareness regarding potential difficulties arising from individual member state implementation of the GDPR based on its opening clauses as well as further emerging EU regulations. <p>ii) Analyse how differing member-state data protection legislation arising from opening clauses may affect data processing for scientific research purposes;</p> <p>iii) Analyse whether there is room for further harmonisation in the context of the respective legislations;</p> <p>iv) Encourage harmonisation taking into account specific legal bases for data processing.</p>	<p>(a) Implication: monitor relevant member state legislation and identify possible room for EOSC policies.</p> <p>(b) Impact: encourage further harmonisation.</p> <p>(c) Impact: essential for the lawful processing of data.</p> <p>(d) Impact: potential to achieve a high standard of data protection for the EOSC.</p>	<p>(e) Implication: funding of relevant actions by EOSC, RPOs and RIs.</p> <p>(f) Impact: essential for the lawful processing of data.</p> <p>(g) Impact: potential to achieve a high standard of data protection for the EOSC.</p>	<p>(h) Implication: encourage harmonisation taking into account legal bases for data processing.</p> <p>(i) Impact: essential for the lawful processing of data.</p>	<p>(j) Implication: raise awareness regarding potential difficulties arising from individual member state implementation of the GDPR.</p> <p>(k) Impact: essential for the lawful processing of data.</p>

Draft Policy Recommendation	EOSC Governance/Rules of Participation	Funders and Ministries	Research Producing Organisations	Research Infrastructures
<p>DP3. Developing a user-friendly EOSC</p> <p>a) Introduction of a special tag for the processing of data in the EOSC (as already done by some stakeholders). We recommend at least a differentiation between</p> <ul style="list-style-type: none"> - personal data - special categories of personal data - data to be processed under special conditions (e.g. the data of minors) <p>b) Introduction of special regimes to classify data according to the level of data protection constraints.</p>	<p>(a) Implication: EOSC governance should introduce special regimes (-> classified according to research area or level of protection).</p> <p>(b) Impact: support for users via identification of the respective regulations.</p>	<p>(c) Implication: funding of relevant actions, particularly by RIs.</p> <p>(d) Impact: support for users via identification of the respective regulations.</p>	<p>(e) Implication: adhere to the measures of the other actors.</p> <p>(f) Impact: Support for users via identification of the respective regulations.</p>	<p>(g) Implication: Introduction of a tag that (at a minimum) differentiates between</p> <ul style="list-style-type: none"> i) Personal data ii) Special categories of personal data iii) Data to be processed under special conditions. <p>(h) Impact: Support for users via identification of the respective regulations.</p>

Draft Policy Recommendation	EOSC Governance/Rules of Participation	Funders and Ministries	Research Producing Organisations	Research Infrastructures
<p>DP4. Education/Consultation</p> <p>i) GDPR training for the staff of research providing organisations and research infrastructures, with emphasis on communication of legal knowledge</p> <p>ii) GDPR training for data subjects (including data donors), with special focus on the rights of data subjects</p> <p>iii) Establishment of one single point of contact for data subjects (in case the EOSC has its own data protection officer, they may take up this role).</p>	<p>(a) Implication: establish one single point of contact for data subjects (potentially the EOSC’s own data protection officer).</p> <p>(b) Impact: benefits due to better understanding of the GDPR among involved actors and data subjects and enhanced trust.</p>	<p>(c) Implication: funding of relevant actions by EOSC, RPOs and RIs.</p> <p>(d) Impact: benefits due to better understanding of the GDPR among involved actors and data subjects and enhanced trust.</p>	<p>(e) Implication: provide data protection training for staff & inform them of legal issues.</p> <p>(f) Impact: benefits due to better understanding of the GDPR among involved actors and data subjects and enhanced trust.</p>	<p>(g) Implication: provide data protection training for staff & inform them of legal issues.</p> <p>(h) Impact: benefits due to better understanding of the GDPR among involved actors and data subjects and enhanced trust.</p>
<p>DP5. Assurance: EOSC should develop a personalised policy catalogue for users</p>	<p>(a) Implication: EOSC governance should develop a personalised policy catalogue that works as a protocol to fulfil the documentation obligation and keeps users informed about relevant changes.</p> <p>(b) Impact: Meets the obligation for documentation under the GDPR and provides the EOSC with a mechanism to keep its users informed.</p>	<p>(c) Implication: funding of relevant actions by EOSC governance, RIs and RPOs.</p> <p>(d) Impact: meets the obligation for documentation under the GDPR and provides the EOSC with a mechanism to keep its users informed.</p>	<p>(e) Implication: Implement and monitor use of the personalised policy catalogue by users.</p> <p>(f) Impact: Meets the obligation for documentation under the GDPR and provides the EOSC with a mechanism to keep its users informed.</p>	<p>(g) Implication: cooperate with users to support their use of the personalised policy catalogue?</p> <p>(h) Impact: meets the obligation for documentation under the GDPR and provides the EOSC with a mechanism to keep its users informed.</p>

ANNEX A. INTERVIEWS CONDUCTED

Heiko Tjalsma 10/04/2018

Rob Baxter 05/04/2018

Jan Korbelt 08/01/2018

The above interviews were conducted to provide a solid foundation of expert knowledge to draw upon when developing data protection policies for the EOsc, knowledge which has also been integrated into this paper. The participants were thus selected based on their knowledge and experience in data protection. The above list contains only the names of those who responded to our inquiry.

The interviews are available upon request.