ROSiE

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# D2.3 Recommendations for addressing social and legal challenges related to OS

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## Project title: Responsible Open Science in Europe

## Project acronym: ROSiE

Grant Agreement no.: 101006430
Lead contractor for this deliverable: University of Latvia

This project has received funding from the European Union's Horizon 2020 research and innovation programme

under GA No 101006430

**Deliverable factsheet:**

| | |
|---|---|
| **Project Number:** | 101006430 |
| **Project Acronym:** | ROSiE |
| **Project Title:** | Responsible Open Science in Europe |
| **Title of Deliverable:** | Recommendations for addressing social and legal challenges related to OS |
| **Work Package:** | 2 |
| **Due date according to contract:** | M28 – 30 June 2023 |
| | |
| **Editor(s):** | |
| **Contributor(s):** | Heidi Beate Bentzen, Teodora Konach, Signe Mežinska |
| **Reviewer(s):** | Tom Lindemann, Søren Holm |
| **Approved by** | Rosemarie Bernabe |
| **ABSTRACT:** | |
| **Keyword List:** | Open Science, social issues, legal issues, intellectual property, recommendations |



This project has received funding from the European Union's Horizon 2020 research and innovation programme under GA No 101006430

Consortium:

| No. | Role | Name | Short Name | | Country |
|---|---|---|---|---|---|
| 1. | Coordinator | University of Oslo | UiO | | Norway |
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| 13 | Partner | University of Porto | U-PORTO | | Portugal |

Revision history:

| VERSION | DATE | Revised by | Reason |
|---|---|---|---|
| **0.1** | 12.06.2023 | Signe Mežinska | Preparation of the 1st draft |
| | | | |



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# Recommendations for addressing social and legal challenges related to Open Science

These recommendations are based on the results of one of the ROSiE project work packages aimed at mapping, analysing, and addressing social and legal implications and challenges related to Open Science in the context of research ethics and research integrity.

Part I of the recommendations "Addressing Intellectual Property Rights" is based on a non-systematic literature review of scientific literature and primary legislative resources, declarations, recommendations, statements, and policy documents. The resources were complemented by the findings of relevant EU-funded projects, the ROSiE project deliverables, and working documents. The critical analysis was aimed at the identification of the main challenges, inconsistencies, and contradictions in the current systems of Open Science practice and Intellectual Property Rights (IPRs) regimes[1], using the constructivist framework.

Part II of the recommendations "Processing data about humans" is based on a deliverable that assessed the legal aspects of open science using a legal dogmatic methodology.

Part III of the recommendations "Addressing social issues" is based on a non-systematic critical interpretive review of the publicly available reports from relevant EU-funded research projects and scientific literature, as well as on the results of focus group discussions organized by the ROSiE project where scientists discussed social implications and challenges related to Open Science.

## I. Addressing Intellectual Property Rights

1. **Develop balanced policies at European, national, and institutional levels.** The Open Science and IPRs frameworks are both very complex systems, therefore, balancing and managing their interactions require a very holistic approach, which is still missing. However, more emphasis should be put on clarifying their synergies and ways of co-existence[2], instead of engaging with radical approaches, as the IPRs play a significant role in securing a valid and very diverse range of rights of authors and inventors, and in setting balanced accessibility, protection, and dissemination rules for over a century. Of course, the rapid technological progress is challenging the existing IP system, nevertheless, there are significant legislative efforts on international and national levels to progressively develop models for securing this alignment.
2. **Promote IPR tools to facilitate, regulate and secure the responsible uptake of Open Science.** Correctly used IPRs are essential mechanisms for introducing, implementing, and strengthening the responsible practice of Open Science. They safeguard not only the valid interests of individuals and groups but also – the privacy and security of parties involved, legitimate private and commercial interests, and the global EU, national and institutional competitiveness[3].
3. **Foster stronger harmonization of IPRs on the EU level.** Drawing on projects like the Wittem Group's European Copyright Code[4], a stronger initiative on the EU level to harmonize existing, diverse IP-related national legislations should be fostered. An EU regulatory and policy framework will enable more concise and standardized protection and will secure the alignment of the IPRs with the ongoing, rapid technological processes, including emerging Artificial Intelligence technologies. This, in turn, will foster a better and clearer understanding of the complex and diverse IPRs tools and

[1] See: Bacchi, C. and Goodwin, S. 2016. Post structural Policy Analysis: A Guide to Practice. NY: Palgrave Macmillan.
[2] See: Cueva, J. and Méndez, E, 2022. Open science and intellectual property rights. How can they better interact?: state of the art and reflections', 2022, Directorate-General for Research and Innovation, Prosperity Directorate, https://ec.europa.eu/info/publications/open-science-and-intellectual-property-rights_en.
[3] See EARTO Paper: Towards a Balanced Approach Between IPRs and Open Science (July 2020), p.7: 'an unbalanced one-size-fits-all European Open Science policy where the concept of Open Science is still too often associated with 'free of charge access for all' would be highly detrimental to European RD&I ecosystem and to the research system itself'. July 2020, accessed online on 7.6.2023: https://www.earto.eu/earto-paper-towards-a-balanced-approach-between-iprs-and-open-science-policy/
[4] See the full text of the 'European Copyright Code' by Wittem group: https://www.ivir.nl/copyrightcode/ecc-pdf/. For information on the initiative see: https://www.ivir.nl/copyrightcode/introduction/.



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mechanisms and will facilitate the development of easy-to-implement strategies for sharing, communicating, disseminating, and re-use of copyrighted works. Special emphasis should be paid to copyright harmonization, as a highly relevant part of the IPR system for all scientific, research, academic, and creative outputs.

4. **Introduce Open Science perspective to the existing informational and administrative bodies.** Some successful initiatives on the EU level in providing information, support, training, and advising on IPRs related issues to all interested parties are already ongoing (i.e., the European IP Helpdesk[5]). Furthermore, the unitary patent[6], which is fostering and boosting technology development and industry uptake in innovation at the EU level, has proved to be a feasible and implementable tool for a number of countries, for reducing legal and administrative complexity and lowering costs. Introducing a focus on (responsible) Open Science practices and IPRs within the already existing structures could be the first step in developing some more specialized structures in the future[7].
5. **Strengthen basic education and knowledge of available forms of IPRs.** Although researchers are already heavily overloaded with multiple tasks and different trainings in additional skills, some basic knowledge of related IPRs (with an emphasis on discipline-related types and forms of protection, not only on copyright) is very much needed, when taking into consideration research activities in the virtual/digital realm, and more specifically within the Open Science framework. Topics to be addressed are essentially related to definitions of work and author, economic and moral rights and their transferability (within the continental IPRs context), types of protection (copyright, patents, contracts, licenses, trademarks, trade secrets, etc.), and their duration.
6. **Mainstream the use of existing best practices and tools.** Data management plans should be mainstreamed, with some accompanying sets of examples and best practices, and – ideally – templates and checklists, in an online, freely accessible format, for uploading and adjustments, with a discipline-sensitive approach. Additional attention should be given to the recognition of discipline-relevant open-source software.
7. **Introduce FAIR principles to not publicly funded research.** Open Science rigour in research processes and management of results in publicly funded projects is already introduced by some of the major funders in Europe (including the European Commission[8]). In the interest of society and the research system, some minimum standards should be negotiated with private funders as – ideally – a more balanced approach should be established. Results of the privately funded research should also contribute to the research system itself and build societal trust in science and be scrutinized by the general public. Allowing significant divergences in the Open Science related practices of data and research result dissemination, sharing, reproduction, etc., might create a serious disadvantage to publicly funded research in terms of economic rights and protection.
8. **Consider costs and environmental challenges – develop a Roadmap for long-term data storage and curation, based on a Cost-Benefit Analysis.** Managing, storing, and curating data for long-term periods is very costly and resource-heavy. A proper analysis to mitigate this extensive spendings, in the current situation and the ongoing environmental challenges, should be carefully developed. These investments have to be properly recognized at institutional, national, and EU levels. Duplicating efforts should be avoided, therefore, an EU-coordinated initiative and standards on responsible, long-term data storage and curation are needed, to holistically and strategically align the efforts between member states and globally.
9. **Strengthen the reach, efficiency, and more user-oriented approach of the European Open Science Cloud initiatives.** To efficiently manage and store data, it is necessary to assess its quality. Resources need to be made available on a continuous basis to ensure data quality because responsible data sharing presupposes that data meet high-quality

[5] European IP Helpdesk: https://intellectual-property-helpdesk.ec.europa.eu/regional-helpdesks/european-ip-helpdesk_en.
[6] See: https://www.epo.org/applying/european/unitary/unitary-patent.html
[7] As suggested in the report of Javier de la Cueva and Eva Méndez on 'Open science and intellectual property rights. How can they better interact?: state of the art and reflections' (p.94). https://ec.europa.eu/info/publications/open-science-and-intellectual-property-rights_en.
[8] See: The initiative Plan S (www.coalition-s.org).



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standards. With many valuable ongoing initiatives, special attention should be given to the meaningful and community-driven strengthening of the European Open Science Cloud on the managerial and project-based levels. Its core values and mission should be mainstreamed, by securing a wider re-opening to end-users, a broader, community-based stakeholders' approach, and more user-friendly, discipline-tailored solutions. As the recent operational framework ends in 2027, a lessons-learned approach in shaping the future of the European Open Science Cloud, as a legal entity and its actions, should be strategically conceptualized.

## II. Processing data about humans

10. **Assess the identifiability of the data, keeping in mind that the threshold for considering data anonymous varies between jurisdictions.** In the EU/EEA, the threshold for considering data anonymous under Regulation 2016/679 (GDPR) is very high. If individuals can be identified in the dataset or through linkage with other datasets, or if the data is uniquely identifiable, the data is personal data and must be processed in accordance with the GDPR. Pseudonymized data remains personal data.
11. **Even if the data is anonymous, consider the impact of the data on groups**, to avoid group discrimination or other forms of misuse.
12. **If depositing data in a research repository, or sharing the data with new researchers/research institutions, consider the following in relation to the GDPR and domestic research ethics legislation:**
    - If required, conduct a Data Protection Impact Assessment in accordance with Article 35 of the GDPR.
    - Assess whether the repository or new user is a new controller, a joint controller, or a data processor, and enter into the necessary contracts in accordance with the roles.
    - Assess which country's courts and which country's laws apply.
    - Ensure that the limits of the ethics approval and the informed consent are respected and that a lawful basis for data processing in accordance with Articles 6 and 9 of the GDPR is in place. For research repositories, assess the procedures for ensuring this for new users.
    - If the repository or new user is based outside the EEA or with an international organization, ensure that a Chapter V GDPR transfer mechanism is in place.
    - For data repositories, assess the procedures for data access. For new users, assess potential onward transfers.
    - Assess the fulfillment of data subject rights, and that personal data is processed fairly and in a transparent manner in relation to the data subject/research participant.
    - Assess the technical and organizational measures, including protection against unauthorized or unlawful processing and against accidental loss, destruction, or damage.
    - Assess the procedures for ensuring that the personal data is accurate and, where necessary, kept up to date.
    - Assess the compliance with the principle of data minimization in Article 5(1)(c), that personal data shall be adequate, relevant, and limited to what is necessary in relation to the purposes for which they are processed.
    - Assess the compliance with the principle of purpose limitation in Article 5(1)(b), that personal data shall be collected for specified, explicit and legitimate purposes and not further processed in a manner that is incompatible with those purposes; further processing for archiving purposes in the public interest, scientific or historical research purposes or statistical purposes shall, in accordance with Article 89(1), not be considered to be incompatible with the initial purposes.
    - Assess the compliance with the principle of storage limitation in Article 5(1)(b), that 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 may be stored for longer periods insofar as the personal data will be processed solely for archiving purposes in the public interest, scientific or historical research purposes or statistical



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purposes in accordance with Article 89(1) subject to the implementation of the appropriate technical and organizational measures required by the GDPR in order to safeguard the rights and freedoms of the data subject/research participant. Assess the fulfillment of your research institution's accountability duties.

- If applicable, assess the procedures for returning research results, including incidental findings, to research participants, and how the rights to know and not to know are respected.

Specific and practical EC guidance addressing all the points above on how both to comply with EU data protection legislation and achieve the aim of open science would be useful to researchers. The European Data Protection Board will in 2023/2024 prepare Guidelines on the processing of data for medical and scientific research purposes, and this may be a useful starting point for such open science guidance.

### III. Addressing social issues

13. **Identify and change cultural attitudes and elements of institutional culture that are potential barriers to the implementation of Open Science practices.** Scientists or institutions may lack motivation and opportunities to change existing power relationships, traditions, practices, and unwritten norms in science which are often based on cultural attitudes and the existing institutional culture that may differ in various cultural and institutional contexts. Social sciences research studies may help identify these potential barriers both at the institutional and national levels. To overcome cultural resistance and to incorporate Open Science practices, management aimed at the internalization of Open Science principles and values, fostering scientists' well-being, as well as supporting scientists in their efforts to open scientific practices, data, and research results is important.
14. **Provide researchers with the necessary resources and infrastructure to support responsible Open Science practices.** The Open Science Framework is infrastructure-heavy and functions at its best in countries with established and operational systems of public-funded research. However, Open Science resources and infrastructure must be accessible and affordable to all researchers, regardless of their location or institutional affiliation. Also, information about existing Open Science infrastructures and resources is crucial for the successful implementation of Open Science practices.
15. **Recognise legitimate differences in attitudes and readiness to engage in Open Science between different fields of science.** Differences between scientific disciplines may be explained by differences in technical skills, traditions, data specificity (qualitative/ quantitative/ sensitive/ personal, etc.), history of practicing Open Science in discipline, etc. Some scientific disciplines have well-developed traditions in Open Science and data sharing and have developed the necessary infrastructure and databases, whereas other disciplines may lack this experience, traditions, and infrastructure. Also, ethical issues in the case of human subject research may affect researchers' willingness and ability to share data. There are also differences in attitudes related to the perception of data, where some scientists may see the research material and data as their personal property.
16. **Recognize the potential for global inequities in access to Open Science infrastructure and act to promote global justice and support the needs of researchers in low- and middle-income countries.** More social sciences research and analysis are necessary to gather data on these needs and attitudes, especially in disadvantaged and less represented groups, e.g., scientists in low- and middle-income countries. For example, costs emerging in the context of Open Science (funding needed for the development of Open Science infrastructure, open publishing, implementation of citizen science, and additional training of researchers) can be a significant economic barrier for developing countries and institutions experiencing financial struggles. The situation where Open Science which initially was aimed at building equality creates new forms of inequality is not acceptable.
17. **Re-evaluate current institutional and national level incentives and evaluation systems to align them with Open Science practices.** The hyper-competitiveness of the academic environment and the existing science assessment systems



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still heavily based on quantitative indicators are additional barriers to responsible practicing of Open Science calling for novel and effective solutions.

18. **Recognize and reward researchers for their contributions to Open Science, such as data sharing, publication of preprints, citizen science, and open access publications**. The predominant evaluation system of scientists and scientific results still heavily relies on quantitative indicators such as citation indexes and impact factors. The Open Science movement aims to shift the focus towards transparency, reproducibility, and collaboration, encouraging researchers to embrace Open Science practices. Evaluation of researchers and research results should be a holistic process that considers a range of factors rather than relying solely on traditional metrics, such as the number of publications and their impact factor, which can still be relevant but should be complemented by more comprehensive indicators. Policy-makers at national and institutional levels should develop new indicators and evaluation systems following the available guidance.[9]
19. **Analyse and address the potential for gender-, ethnicity-, age-, disability-related and other biases in research and act to ensure that responsible Open Science practices promote equality and diversity.** At the national and institutional level, when developing policies and diversity action plans for the research environment addressing inequalities based on gender, ethnicity, age, socio-economic status, disability, career stage, etc., issues related to Open Science should be addressed and included in these plans. An open question is why and how different types of inequalities impact the practicing of Open Science and vice versa and this aspect still needs further research.
20. **Promote Open Science practices in the industry sector.** Industry researchers may encounter fewer opportunities and incentives to engage in Open Science practices due to the restrictions imposed by industry sponsors, who typically follow a more closed model of data management than academic environment.

[9] Evaluation of Research Careers fully acknowledging Open Science Practices. Rewards, incentives and/or recognition for researchers practicing Open Science. European Commission. Directorate-General for Research and Innovation. Open Science and ERA Policy Unit, 2017



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