Science Europe Position Statement

On the Proposed European General Data Protection Regulation

May 2013

SCIENCE EUROPE
Shaping the future of research

Science Europe Position Statement on the Proposal for a Regulation of the European Parliament and the Council on the protection of individuals with regard to the processing of personal data and on the free movement of such data (General Data Protection Regulation)

Executive Summary

The European Institutions are currently entering the crucial stage of the legislative process that will revise the EU Data Protection Directive and lead to the European General Data Protection Regulation (DPR).

Scientific research produces high impact results, depending heavily on access to and use of datasets that include personal data.

In order to continue to perform scientific research for the benefit of Europe and its citizens, researchers need an appropriate DPR that reconciles the safe processing of personal data for scientific research and the protection of individual rights to privacy.

In this Position Statement Science Europe outlines support for provisions within the Regulation that facilitate scientific research. It is of the utmost importance that the needs of scientific research with respect to accessibility and processing of personal data are considered, that the provisions and derogations that facilitate scientific research are maintained, and that amendments which would dramatically weaken these provisions are rejected. The Statement thus provides concrete recommendations to contribute to the elaboration of an appropriate legal framework for personal data protection in the EU. Science Europe believes that the new Regulation should reconcile the protection of individual rights to privacy with the safe processing of personal data for scientific purposes. A failure to strike the right balance would have major implications for a large number of different scientific research activities across Europe and would significantly reduce capacity for innovation and competitiveness.

The societal benefits that result from scientific research and its outcomes are urgent and compelling for the wellbeing of European citizens. The processing of personal data for research purposes therefore deserves particular attention. Decades of academic research have demonstrated that such research can be conducted robustly in secure environments, in ways that prevent the identification of individuals and protect their privacy without creating additional administrative burden.

Therefore, Science Europe urges European legislators to incorporate the specific needs of the different research domains, to allow scientific breakthroughs and innovative solutions for the benefit of Europe and its citizens, now and in the future.

To support the important work of the legislators, Science Europe offers the expert knowledge of its Member Organisations and Scientific Committees.

Introduction

The European Union (EU) is currently revising the legal framework for the processing and free movement of personal data. The revision is motivated by a need to reduce legal fragmentation among Member States and thus to improve the right to privacy accorded to EU citizens, without impeding the functioning of the internal market.

The European Commission issued its proposal for a General Data Protection Regulation (DPR) in January 2012. The Commission proposes a Regulation rather than a Directive, meaning a single piece of legislation directly applicable at national level. The Commission proposal contains a number of provisions and exemptions crucial to facilitating vital scientific research, thereby reconciling the benefits to society resulting from scientific research with a framework of protection of individual rights to privacy.

Science Europe supports the provisions and derogations within the Commission's proposal which aim to facilitate scientific research, and issues this Position Statement as the European Institutions enter the crucial stages of the legislative process. As European Parliamentarians consider the amendments that have been proposed to the DPR it is of the utmost importance that the needs of scientific research with respect to accessibility and processing of personal data are considered, that the provisions that facilitate scientific research are maintained, and that amendments which dramatically weaken these provisions are rejected.

Personal Data is of Critical Importance in Maintaining and Advancing European Scientific Research

Scientific researchers across Europe, in particular in the social sciences, medical sciences, life sciences and humanities, produce high-impact, world-leading research results with huge societal benefit, which heavily depend on sharing and processing of datasets which include personal data.

In order to continue to perform excellent science for the benefit Europe's citizens, researchers need a DPR that reconciles the safe processing of personal data for scientific research purposes with the protection of the rights and privacy of individuals. The different European institutions and legislators must take into account the increasing advancement in technology and analytical methods of data production, mining and archiving that are essential to enhance further and continuous progress in research.

Science Europe wishes to stress the importance of getting this balance right, and to alert European institutions to the devastating implications of amendments that disturb this balance and would dramatically weaken the provisions and exemptions applicable for scientific research.

Recommendation 1

Science Europe calls on the EU institutions to structure the legal framework for data protection so that, whilst ensuring the rights and privacy of individuals, it facilitates scientific research in Europe, in order to realise the high societal benefits that accrue from it.

Recommendation 2

Science Europe supports Article 83 of the Proposal and its associated provisions and derogations and calls upon the EU institutions to maintain the provisions of Article 83 as proposed by the European Commission, and to ensure that all associated derogations for scientific research are retained and further clarified.

Recognising the Different Types of Personal Data Processed in Scientific Research and the Need to Regulate them Proportionally

The processing of personal data for scientific research purposes in Europe is carried out under high standards of protection of individuals. Scientific research that relies on personal data is conducted within a robust ethical framework and follows internationally-recognised guidelines. Protecting individual privacy and undertaking bona fide scientific research of public benefit are compatible objectives. Scientific research projects that intend to process identifiable personal data undergo review by an independent ethics committee or review board. The overarching role of ethics committees is to ensure that a balance between risks and benefits in the proposed research is struck, so that personal data of a patient or citizen are only processed when this is proportionate to the potential benefits to society as a whole.

Robust methods for managing and undertaking scientific research on individual data exist, such that valuable research can be conducted whilst protecting the privacy of individuals' privacy. Whenever possible, data processed for scientific research purposes are anonymised or treated, in order to conceal the identity of the individuals, using pseudonymisation techniques.

Anonymisation involves disconnecting the data entirely from the subjects. Pseudonymisation involves replacing personal identifiers, such as name, address date of birth or national identity number, with a key or unique identifier allowing individuals to be linked across different datasets without identifying them personally. In addition to protecting the identity of individuals, existing standards for scientific research usually demand that pseudonymised data are stored securely and separately, and managed carefully. Pseudonymised data without access to decryption 'keys' make the possibility of re-identification of individuals very unlikely.

A summary of how identifiable, anonymised and pseudonymised data are used in medical and health research is provided in an Opinion Paper on the DPR from the Medical Sciences Committee of Science Europe.

Recommendation 3

Science Europe asks the EU institutions to acknowledge that scientific research operates within a robust ethical framework that allows balancing risks and benefits of research projects, and that ensures privacy protection.

The level of privacy protection determined by the characteristics of different types of scientific research data (identifiable, pseudonymised, anonymised) needs to be recognised and clarified in the legislation.

Recommendation 4

Science Europe believes that anonymisation must be explicitly stated to be outside the scope of the Regulation.

Clarity is required concerning how the definition of 'personal' data in the proposed regulation relates to 'pseudonymised' data.

Science Europe recommends adoption of a risk-managed approach in the case of pseudonymised data, recognising explicitly that they require a level of protection between that of identifiable and anonymised data.

Recommendation 5

When re-identification from pseudonymised data is needed, Science Europe recommends a case-by-case approach with guardians, clear procedures and appropriate controls for re-identification using specific decryption 'keys'. These procedures should build on existing, well-established, state of the art procedures used in many European centres of excellence for data processing.

Recognising the Specific Aspects of Individual Consent and Personal Data Privacy in the Context of Scientific Research

Science Europe welcomes the high visibility given to consent in the proposed DPR, as consent can be the basis for trust. Informed consent by subjects whose data is being processed for scientific research purposes is a key ethical requirement for investigators. Informed, specific, explicit consent should be the norm, sought wherever this is possible and where it does not lead to a disproportionate burden that may risk preventing important scientific research from being carried out.

Science Europe wishes to draw the attention of the EU institutions to the fact that for some research projects it is not possible to seek consent at all from study participants. Examples relating to medical and health research are discussed in the Opinion Paper from the Science Europe Medical Sciences Committee and include emergency care research, where many subjects are physically unable to give consent; studies where a very large sample size is needed for obtaining a robust result, which makes it practically impossible to seek specific, explicit, informed consent; or studies where seeking consent would actually introduce bias and distort the research findings. In such cases, ethics committees play a critical role and may decide on strong ethical grounds that the personal data of a study subject may be processed without consent.

Another key aspect of cross-European scientific research is the establishment of large population cohorts and related bio-banks infrastructures, where longitudinal data and biological samples are systematically collected from individual that give their 'broad consent' for their pseudonymised data to be used for a variety of research studies. In this way the burden on study participants is kept to a minimum as study participants do not have to

re-consent each time, and the data they provided for scientific research can be re-used many times by many different researchers, thus maximising the benefits of public investment in scientific research.

Recommendation 6

Science Europe urges the EU institutions to acknowledge the specificity of the requirements for consent in scientific research, and to maintain derogations of Article 83 allowing for processing of appropriately-protected personal data for scientific research without consent, or by using 'broad consent' procedures if they are practical.

Limiting the Administrative and Legal Burdens Associated with Personal Data Privacy for Scientific Research

Compared to the current Data Protection Directive, the proposed DPR includes specific provisions for data storage (Article 5e), the right to information (Articles 14 and 15), the right to rectification (Article 16) and impact assessment (Articles 33 and 34), all of which have the potential to considerably increase the administrative and regulatory burden for research without providing further levels of individual protection in an already highly regulated area.

Recommendation 7

Science Europe stresses the crucial need for a DPR that does not increase the administrative burden for scientific researchers and research organisations.

Specifically, the DPR should not require periodic review of research data stored in research institutions; disproportionate demands on researchers to provide information to data subjects should be avoided; requirements to rectify data should be balanced and should avoid disproportionate administrative burden; and impact assessments undertaken by a suitable national authority should be accepted without the need for additional assessments.

Examples from Different Scientific Research Fields

Routinely-collected data of individuals are a vital resource for academic research across a wide range of disciplines. Such data underpin observational, often longitudinal, studies and have led to significant advances that would have been otherwise impossible.

In the **Social Sciences**, for example, studies using personal data have produced invaluable insights into: socio-economic variations in access to higher education; the effect of parental separation on children's educational attainment; socio-economic variations in alcohol-related mortality following the introduction of minimum alcohol pricing; economic analyses of proposed banking reforms on small and medium-sized firms; and the behavioural patterns of stock market investors. Results have led to an evidence base at the disposal of

policy makers to address key societal challenges in Europe today. Producing key evidence of this type would become much more difficult without the appropriate provisions for scientific research in the DPR.

Examples in **Medical Studies** (including studies of **Life Sciences**) include work that has: demonstrated the long-term value of drug interventions beyond the end of clinical trials; compared hospital death rates; helped tease out the role of genetics and environment in disease; and undertaken pharmaco-epidemiological research on prescriptions databases. Results have led to more effective treatments for many diseases, including chronic diseases. They provide scientific evidence for policies that help make health-care systems more efficient and less costly. They have opened the way for new breakthroughs in personalised medicine and enhancing the quality of life of citizens. In many studies, interesting correlations that lead to breakthroughs only become apparent after the initial results suggest the implications of new variables that were not taken into consideration at the time of the study design. Discovery of new phenomena occurs only after going back to the original patient files and stratifying them according to the new variables. This type of analysis – which would not have been possible under data protection rules that prevent re-linking data and individuals – has led to the identification of new susceptibility genes for diabetes or new groups of patients that present different outcomes after breast cancer.

In the **Humanities**, scientific research relies heavily on the collection, retrieval and analysis of personal data. Examples include: work on language diversity based on speech recordings; studies of cultural innovation, using an interaction design involving individuals and groups; and research on historical transformations based on archival material such as letters, diaries, family photographs and other personal visuals. Research of this type has led to a significantly better understanding of the social transformations that have shaped Europe and of the processes of cultural and social identity formation which underly these.

Conclusion

European scientific research in various domains will fall behind our international competitors without a clear, well-thought-out approach by the European Institutions in the legislative process for the Data Protection Regulation.

Therefore, Science Europe urges European legislators to incorporate the specific needs of the different scientific research domains, to allow scientific breakthroughs and innovative solutions for the benefit of Europe and its citizens, now and in the future.

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Recommendations Overview

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Science Europe is a Brussels-based association of 51 European national research organisations. It was founded in October 2011 with the aim of promoting the collective interests of members and providing them with a platform to collaborate at both policy and activity level. More information is available at www.scienceeurope.org

Science Europe
Rue de la Science 14
B-1040 Brussels

Tel: +32 (0)2 226 03 00
Email: office@scienceeurope.org
www.scienceeurope.org

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