



EUROPEAN SOCIETY OF HUMAN GENETICS



STATEMENT ON THE EP REPORT ON

THE PROTECTION OF PERSONAL DATA



On behalf of the European rare disease community at large, we hereby express our deep concern on the Draft Report, released on 16 January 2013, by Jan Philipp Albrecht (Greens/European Free Alliance, Germany) on the protection of individuals with regard to the processing of personal data and on the free movement of such data, the so-called Data Protection Regulation.



Among the 350 amendments proposed, a consistent number would have disastrous implications for health research starting from the disconcerting premise that: *“Processing of sensitive data for historical, statistical and scientific research purposes is not as urgent or compelling as public health or social protection. Consequently, there is no need to introduce an exception which would put them on the same level as the other listed justifications.”*⁽¹⁾



This premise contradicts the international efforts to enhance and promote health research at global level. It would be consistent for the EU to recognise the statements made by the Presidential Commission for the Study of Bioethical Issues in its report on Privacy and Progress in Whole Genome Sequencing (WGS)²: “The potential exists for rapid advances in (...) healthcare resulting from WGS. Essential to achieving those advances is the need to share, compare and pool data”. Therefore, “the Commission recommends strong baseline protections for WGS data to protect



¹ Justification to Amendment 27 of the proposed Recital 42

² Washington, D.C. October 2012, www.bioethics.gov

individual privacy and data security while also leaving ample room for data sharing opportunities that propel scientific and medical progress”.

We strongly believe, as do other European stakeholders involved in health-related fields, that scientific research is an undeniable priority in order to advance and guarantee public health and social protection. If certain crucial amendments were to be accepted (e.g. Amendments 13-14; Amendment 27; Amendments 84-85; Amendments 327-328; Amendments 334-337), it would be the end of health research progress in Europe.

Among the most affected research tools, there would be disease registries, often created at the initiative of and supported by patient groups, together with medical experts. Registries represent fundamental research tools. Registry-based research - often supported by EU funding - has been at the core of great advances in understanding human diseases over the last 15 years. Registries are also needed for medical genetic diagnostics, family counselling and follow-up, and increasingly so for the treatment of rare diseases, an estimated 80% of which is genetic in origin.

Registry-based research would most likely become unmanageable under the proposed amended regulatory framework that sets up an unattainable high bar for all but the most exceptional circumstances (e.g. bioterrorism) and would significantly increase the regulatory burden on organisations using pseudonymised data or willing to share these data with collaborators in countries outside the EU. This would represent a major setback especially for research on rare diseases where collaboration and optimal use of scarce resources and data are particularly necessary at both the European and International levels. Therefore, missing the opportunity of exploiting and sharing the limited amount of data that are collected would dramatically delay the improvement of health care for European citizens living with a rare disease. It would *de facto* result in discrimination against rare disease patients regarding their fundamental right to quality health care and would pose serious ethical problems.

Therefore, we urge Members of the European Parliament to consider the following three points:

- 1. It is essential that Article 83 be maintained within the Regulation, as pertains to health and sensitive data in order to facilitate health research;***
- 2. It is fundamental that the amendments clarify and strengthen the research provisions in order to ensure that the Regulation establishes a health research-friendly framework in Europe while striking the right balance with personal data protection;***
- 3. The scope of the Regulation should be clarified in order to ensure that the use of pseudonymised data in health research is regulated in a proportionate manner.***

It is of fundamental importance to balance privacy rights with the right to protection of health and to bear in mind the ethical value of solidarity in sharing data to provide better health to others.

Health research is essential for public health and health care. The benefits are manifold: to capitalise on these benefits, ***it is vital that the EU strikes an appropriate balance between facilitating the safe and secure use of patient data for health research and the rights and interests of all individuals.***

Support to the statement provided by:

→ European organisations and consortia

- [EURenOmics](#) - Consortium devoted to improving the lives of patients affected by rare kidney diseases
- [European Academy of Bozen/Bolzan](#) - EURAC
- [European Platform for Rare Disease Registries](#) - EPIRARE
- [European Society of Human Genetics](#) – ESHG
- [NeurOmics](#) - Integrated European Project on Omics Research of Rare Neuromuscular and Neurodegenerative Diseases
- [Orphanet](#) – The portal for rare diseases and orphan drugs
- [RD-Connect](#) - An integrated platform connecting databases, registries, biobanks and clinical bioinformatics for rare disease research

→ International organisations

- [Genetic Alliance](#)
- [Public Population Project in Genomics and Society](#) - P3G

→ Non- European Patient organisations

- [Canadian Organization for Rare Disorders](#) – CORD
- [National Organization for Rare Disorders](#) – NORD
- [New Zealand Organisation for Rare Disorders](#) – NZORD
- [Rare Cancers Australia](#)
- [Rare Voices Australia](#)