

Protecting health and scientific research in the Data Protection Regulation (2012/0011(COD))
Position of non-commercial research organisations and academics – April 2014

Health and scientific research will be severely threatened if the [amendments to Articles 81 and 83 of the Data Protection Regulation adopted by the European Parliament](#) are taken forward. Scientific research generates important benefits by improving our understanding of society, health and disease. If implemented, the amendments would make much research involving personal data at worst illegal, and at best unworkable.

In order to protect valuable research while protecting privacy, we urge:

- **the Council of Ministers to maintain the Commission's text on Articles 81 and 83 and associated provisions when agreeing its general approach;**
- **MEPs to seek a more positive outcome for research in trilogue negotiations; and**
- **the Council of Ministers and European Commission to oppose the European Parliament's amendments to Articles 81 and 83 in trilogue negotiations.**

The original draft Regulation set out a proportionate mechanism for protecting privacy, while enabling health and scientific research to continue. It included a requirement for specific and explicit consent for the use and storage of personal data, but provided an exemption for research, subject to certain safeguards in Article 83. This recognised that individuals' interests can be protected through strong ethical and governance safeguards, such as approval by a research ethics committee.

The European Parliament's amendments to Articles 81 and 83 very significantly reduce the scope of this research exemption. The use of personal data in research without specific consent would be prohibited or become impossible in practice. The requirement for specific consent fails to take account of the fact that this research is subject to ethical approval and strict confidentiality safeguards, and the identity of individuals is often masked.

This would put at risk significant European investments in genetics, cohort studies, biobanks, disease registries and the use of routinely collected data, and associated progress towards understanding society, health, and disease that delivers real patient benefit.

Further information is included on pages two and three, with detailed technical comments on the amendments adopted by the European Parliament provided in Annex A.

QUESTIONS AND ANSWERS

Why are personal data so important for research to improve public health and healthcare?

Personal data, such as individual patient records, provide a vital resource for research for the benefit of society and saving and improving the lives of patients. For example, personal data allow researchers to compare different factors, such as lifestyle, and the incidence of disease at an individual level. These observational studies have led to breakthroughs such as identifying the association between smoking and lung cancer and informing treatment of infection in unborn babies.

How do researchers safeguard confidentiality?

Research using personal data should only take place within a robust ethical and governance framework to ensure that an individual's personal data are only used in research when this is proportionate to the potential benefits for society as a whole. Researchers are given access to personal data only under strict confidentiality controls, which have been effective at preventing misuse and harm to data subjects.

Why will the European Parliament's amendments prevent health research?

LIBE amendments 86, 191 and 194 to Articles 81 and 83 would:

- make it very difficult, if not impossible in practice, to use pseudonymised data concerning health – where an individual's identity is masked to protect privacy – without specific consent; and
- prohibit the use of identifiable personal data in scientific research without specific consent. Researchers only use identifiable data without consent where other approaches are not practicable and this is currently only allowed subject to ethical approval and strict confidentiality safeguards. Sometimes researchers need details such as age, postcode and information on a health condition that together could disclose the identity of an individual, but the study would not be possible without it. Further explanation of our concerns is provided in Annex A.

How would data subjects be protected without the European Parliament's amendments?

The amendments are intended to protect data subjects in research but there are other, better ways to achieve this. A rigorous regulatory and governance framework for research already exists, enshrined in national and international laws, and researchers follow guidance built on strong ethical principles. The amendments are therefore not necessary to protect data subjects. However, the Regulation could be strengthened to clarify the important role of existing safeguards, such as project approval by an independent ethics committee.

What type of research would the European Parliament's amendments put at risk?

The amendments will make much health research involving personal data at worst illegal, and at best unworkable. This research has the potential to deliver further gains in our understanding of common chronic diseases that affect large numbers of European patients, such as Alzheimer's disease and cancer.

The amendments will put at risk significant European investments in genetics, cohort studies and the use of routinely collected data, such as:

- The European Prospective Investigation into Cancer and Nutrition (EPIC), the largest study of diet and health ever undertaken, involving over half a million European citizens, which uses broad consent from participants to allow researchers to access relevant data through rigorous governance arrangements.
- The European Medical Information Framework, a €56 million project to link together existing health data from sources across Europe to make this wealth of information available to researchers for studies on obesity and Alzheimer's disease.
- The Human Brain Project, which aims to use existing data to model how the brain works and catalyse a global collaborative effort to understand the human brain and its diseases.

The amendments will also affect research on important economic and societal issues, which often relies on data from a range of sources collected over many years, such as:

- The European Social Survey, which measures opinions and behaviours across more than thirty European countries to inform policy in areas such as health inequalities and economic instability.

In many studies that will be affected, individuals have voluntarily given broad consent for their data to be used in research to further our understanding of society, health and disease. Their valuable contributions could be wasted if the amendments become law.

What steps are needed to protect research and its benefits?

It is vital that the Commission's original research provisions are maintained to ensure that the Regulation strikes an appropriate balance between facilitating the safe and secure use of personal data in research and the rights and interests of individuals.

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What are the next steps in the legislative process?

The amendments adopted by the European Parliament form Parliament's position ahead of the next stage of the legislative process. The Council of Ministers must also agree a position and authorise the Presidency to negotiate on its behalf. Once the Council of Ministers has adopted a position, the European Parliament, Council of Ministers and European Commission can enter the 'trilogue' process to negotiate a final draft to vote on.

Signatories

Academy of Medical Sciences UK	European Organisation for Research and Treatment of Cancer (EORTC)	Northern Ireland Biobank
Alexander von Humboldt-Stiftung	European University Association	Nuffield Foundation
Alliance for European Diabetes Research (EURADIA)	Farr Institute of Health Informatics Research	Parkinson's UK
Arthritis Research UK	Federation of European Academies of Medicine	PHG Foundation
Association of Community Nursing (Spain)	Fraunhofer-Gesellschaft	Public Health Association (Canary Islands, Spain)
Association of Health Administration (Madrid, Spain)	French National Academy of Medicine	Public Health Association (Catalonia, Balearic Islands, Spain)
Association of Health Economy (Spain)	Genetic Alliance UK	Public Health Association (Madrid, Spain)
Association of Medical Research Charities	German National Academy of Sciences Leopoldina	Public Population Project in Genomics and Society
Biotechnology and Biological Sciences Research Council	Global Alliance for Genomics and Health	Psychiatric Epidemiological Association (Spain)
Breast Cancer Campaign	Health and Social Care, Northern Ireland	Research Councils UK
British Association for the study of the Liver	Health Law Association (Spain)	Royal College of Physicians
British Heart Foundation	Health Research Board (Ireland)	Royal Society of Edinburgh
British Society of Gastroenterology	Helmholtz Association	Russell Group
Cancer Research UK	Hipatia (Spain)	Science Europe Medical Sciences Committee
Czech Medical Academy	Hochschulrektorenkonferenz	Spanish Environmental Health Association
Deutsche Zentren der Gesundheitsforschung	Hungarian Academy of Sciences	Spanish Network of Primary Health Care
Deutsche Forschungsgemeinschaft	Independent Cancer Patients' Voice	Spanish Society of Epidemiology
Deutscher Akademischer Austauschdienst	Inserm	UK Higher Education International Unit
Diabetes UK	Institut Pasteur	UKCRC Registered CTUs Network
Economic and Social Research Council	Institute of Cancer Research	United European Gastroenterology
EGAN (Patients Network for Medical Research and Health)	Intensive Care Society	Unique (Understanding Chromosome Disorders)
Engineering and Physical Sciences Research Council	International Cancer Genome Consortium	Universities UK
Epilepsy Research UK	Irish Universities Association	University of Salford
EUROCAT: European Surveillance of Congenital Anomalies	Italian National Academy of Medicine	Vetenskapsrådet / Swedish Research Council
EuroCoord	Leukaemia & Lymphoma Research	VolkswagenStiftung
European Academy of Allergology and Clinical Immunology	Leibniz-Gemeinschaft	VSOP (Association of Cooperating Parent and Patient Organisations)
European Academies Science Advisory Council	Macmillan Cancer Support	Wellcome Trust
European Association of Research Managers and Administrators	Max-Planck-Gesellschaft	Wellcome Trust Sanger Institute
European Association for the Study of Diabetes	Medical Research Council	Wissenschaftsrat
European League against Rheumatism	Medical Schools Council	Yorkshire Cancer Research
	Motor Neurone Disease Association	ZonMw / The Netherlands
	Natural Environment Research Council	Organisation for Health Research and Development
	Nederlandse Federatie van Universitair Medische Centra	
	NHS European Office	

CONTACT

Dr Beth Thompson, Policy Adviser, Wellcome Trust
 T: +44 (0) 20 7611 7303
 E: b.thompson@wellcome.ac.uk



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