

Ensuring a healthy future for scientific research through the Data Protection Regulation 2012/0011(COD)

Position of academic, patient and non-commercial research organisations – June 2015

Personal data provide a vital resource for health and other scientific research to benefit society and save and improve the lives of patients. **It is essential that the European institutions find a compromise position that enables vital research to continue under the Data Protection Regulation.**

We ask the Council of Ministers, European Parliament and European Commission to **demonstrate their shared commitment to research by finding a compromise position, in trilogue negotiations, that:**

- **maintains important exemptions for health and scientific research**, including an alternative means to allow processing of personal data for research where consent is not practicable;
- **includes proportionate safeguards to protect data subjects' interests** and ensure exemptions are used appropriately; and
- **seeks harmonisation where possible, but allows necessary flexibility for Member States** to implement culturally and socially acceptable solutions.

European Commission January 2012

Positive position for research, recognising that specific consent is often not possible, but would be strengthened by clarifying safeguards for data subjects

European Parliament March 2014

Highly damaging position for research as scope of the research exemptions is significantly reduced, particularly for data concerning health

Council of Ministers June 2015

Positive position for research as key exemptions are maintained, with increased safeguards for data subjects and Member State flexibility

Key issues for trilogue

Exemptions for research

- The research community values the privileged position of research in the current Data Protection Directive, which has been essential to allow the safe use of personal data in research.
- The Commission's proposal provides important research exemptions and allows research with personal data – including data concerning health – to take place without consent where the conditions of Article 83 are met. These exemptions have been maintained in the Council's text.
- We are very concerned that the Parliament's position has significantly reduced the scope of the research exemptions. If implemented as drafted, this would have severe unintended consequences by restricting and preventing vital research studies.

Appropriate safeguards to protect data subjects

- Important ethical and governance safeguards, such as approval by a research ethics committee, exist to ensure that data subjects are protected in research.
- We appreciate Parliament's concern that the Commission's proposal does not adequately reflect the importance of such safeguards, and welcome the emphasis on appropriate safeguards in the Council's position.
- We ask the European institutions to find a solution that permits the breadth of the exemptions in the Commission proposal, but introduces further, proportionate safeguards to ensure personal data are used safely and securely in research and prevent misuse of the research exemptions.

Flexibility and harmonisation

- The Parliament and Council have delegated some research provisions to Member States.
- Harmonisation to appropriate standards would be desirable to promote research collaboration.
- However, we recognise the challenges of harmonisation at the present time and the need for flexibility to allow Member States to implement culturally and socially acceptable solutions.

Further detail, including [a joint position paper on the Parliament's amendments](#), is available at wellcome.ac.uk/dataprotectionregulation and on request.

CONTACT

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

Signatories to the statement



CONTACT

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

Position of academic, patient and non-commercial research organisations – June 2015

**RUSSELL
GROUP**

**SCIENCE
EUROPE**
Medical Sciences Committee

SCSP
Sociedad Canaria de Salud Pública

SE
SOCIEDAD
ESPAÑOLA DE
EPIDEMIOLOGIA



SESPAS
SOCIEDAD ESPAÑOLA DE SALUD PÚBLICA
Y ADMINISTRACIÓN SANITARIA



Cancerfonden
Swedish Cancer Society



Understanding
chromosome
disorders
Unique

Universities UK

**University
of Glasgow**
Clinical Trials Unit



wellcometrust

wellcome trust
sanger
institute

yorkshire cancer
research

CONTACT

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