European Parliament supports data protection reforms

The European Parliament has voted for amendments to draft personal data protection regulations that campaigners say will hamper medical research if passed into law. Becky McCall reports.

Reforms on the use of personal data for medical research purposes are one step closer to being made law after the European Parliament (EP) voted in favour of amendments on March 12.

The initial draft of the new Data Protection Regulation proposed by the European Commission (EC) set out a mechanism for protecting privacy while facilitating research. It included a requirement for specific and explicit consent to be gained for the use and storage of personal data, but provided an exemption for research, subject to specific safeguards, such as approval by a research ethics committee. However, amendments tabled by the Civil Liberties, Justice and Home Affairs (LIBE) committee of the EP led by Member of the EP Jan Philipp Albrecht, propose that the use of personal data in research without specific consent should be prohibited unless it falls within a narrow exemption.

The recent vote which concerns all personal data, medical and other, resulted in 621 votes in favour and ten against, and means that LIBE’s proposals have been accepted by the EP and will now await discussion by the Council of Ministers and the EC for a final text. If passed later in the year, the reforms will then become binding as European law.

LIBE wants to see individual patient consent for every new research project, with the exception of research of high public interest. Albrecht tells The Lancet that research based on personal health data would still be possible without the consent or even the knowledge of the person if the work was deemed to be important enough for public health. “How this is exactly done will still be left to the Member States to decide in their own laws”, he adds.

But Richard Frackowiack, who chairs the medical scientific committee of Science Europe, an association of European research organisations, says that this proposal “will cause massive bureaucratic delays and will seriously affect European competitiveness in medical research”.

Beth Thompson, policy adviser at the Wellcome Trust, UK, has been rallying various pan-European research organisations in a united voice against the proposed reforms. Their position is outlined in a statement to the EP with over 70 signatories. In response to the vote, Thompson says: “We are extremely disappointed that the damaging amendments relating to research have made it into Parliament’s position on the Regulation. However, we urge European institutions to ensure these amendments are rejected in the trilogue discussions [the EP, the Council of Ministers, and the EC].”

Current safeguards for the use of personal data research are substantial, encompassing measures relating to limited access to data and protection of the privacy of participants. “The initial European Regulation provided an exemption for research from the requirement for specific consent under specific conditions”, explains Thompson.

If the amendments become legally binding then consent terms for research need to be “specific, explicit, and informed”.

“This concept of ‘specific’ is not compatible with the broad consent models used by researchers, for example those used in longitudinal studies, where consent is given broadly for health research and overseen by robust governance and ethics committees”, she says. “These amendments would be hugely limiting. With a cohort of half a million, such as in UK Biobank or the EPIC [European Prospective Investigation into Cancer and Nutrition] study, requiring consent every time is impractical.”

Frackowiack says that the initial EC proposal understood the benefit to European Union citizens of medical research for personal and public health. “It understood the problem was complex and wrote efficient and useful derogations for such research, relying on a longtime, well used, ethical permissions infrastructure for approval of research projects.”

He says that LIBE, however, has taken a one-sided view, favouring privacy above all else and made modifications to the exemptions that would effectively “suppress or make impractical large areas of public health research, including those of orphan diseases and epidemiological surveys as well as cancer registries”.

Commenting after the vote, Susan Kentner, director of the Brussels Office of the Helmholtz Association of German Research Centres, said that the issues around personal data protection had become unnecessarily entangled with wider issues. “Current data protection legislation dates back to 1995 when the internet and associated issues were little known. I agree it is time to rethink data protection broadly, but medical data issues are being dragged into issues with internet security.”

“However, a co-decision process has yet to take place. With continued hard work and persuasive powers, there is still a glimmer of hope”, she said.

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