

The below response was submitted online in response to the Ministry of Justice's review of the balance of competences around information rights in June 2014.

Question 4: What evidence is there that proposals for a new EU Data Protection Regulation will be advantageous or disadvantageous to individuals, business, the public sector or any other groups in the UK?

The Academy of Medical Sciences promotes advances in medical science and campaigns to ensure that these are translated into healthcare benefits for society. Our elected Fellowship includes the UK's foremost experts drawn from a broad and diverse range of research areas. The use of information on patients and individuals is crucial for many studies in the medical sciences. Data from medical records, other administrative sources and standalone studies (on individuals enrolled in cohort studies, for example) are used to identify the burden and causes of disease, to enrol participants in clinical trials, to help assess the efficacy of treatments and interventions, and to help design local, regional or national policy changes to mitigate disease risks to the population. These data therefore underpin much of the research that benefits society.

The UK's legislative framework on data protection must strike a balance between the need to protect individuals' privacy and allowing the use of personal data for vital medical research. Broadly speaking, the UK's interpretation of the current European Data Protection Directive (1995) (DPD), has permitted an appropriate balance in this respect – in combination with safeguards for patient data from the Data Protection Act (1998), approval from Research Ethics Committees and, in some instances, approval by the Confidentiality Advisory Group. However, we would also highlight that the complexity of the legal framework for the use of personal data in the UK has caused some delays to research studies.

Articles 81 and 83 of the DPR could have profound implications for the conduct of scientific research in the UK. In January 2012, the European Commission published a draft Regulation. Articles 81 and 83 of this draft contained important derogations for scientific, health and statistical research in relation to the requirement for specific and explicit consent by participants to be obtained for studies, if certain safeguards for personal information are met. We were broadly in agreement with the position described in the Commission's draft Regulation in this respect, which struck a proportionate balance between upholding individuals' privacy and allowing the use of personal data to enable the conduct of critical health and scientific research, bearing in mind the requirement for practicable collection of participants' consent. Consent is a paramount ethical principle and researchers seek consent for the use of identifiable data, or use anonymous data, whenever possible. However, it is not always feasible to seek consent for some types of studies, particularly where it is required to be specific and explicit. These include cohort studies, biobanks and disease registries, which allow for the use and re-use of regularly collected data. This kind of research is subject to ethical approval and strict confidentiality safeguards, and the identity of individuals is often masked to the researchers conducting the work.

However, the amendments to Articles 81 and 83 approved by the European Parliament in March 2014 have substantially narrowed the scope of the research-related derogations regarding

consent. Health and scientific research will be severely threatened if these amendments are retained in the final text. As the negotiations between the Council of Ministers, Parliament and Commission progress, the UK Government should seek to ensure that the derogations set out in the Commission's original draft are protected.

The DPR could potentially enable greater clarity and closer harmonisation of data protection law across the EU, giving a common framework for the use of data in research. The current DPD has been subject to varied interpretations between Member States. If a Regulation with a sound balance between research interests and individuals' privacy were implemented, it could facilitate research efforts across Member States and help the UK to maintain its strong position in biomedical science. However, careful negotiations with the EU's Council of Ministers, Parliament and Commission will be required to achieve this and consequently ensure that the UK's global competitiveness in research conduct is not harmed by the implementation of the new Regulation. The Department of Health, Department of Business, Innovation and Skills, and the Ministry of Justice have recognised these concerns and we welcome their ongoing efforts for a positive outlook for UK research, which we hope will continue.

The Academy has been working alongside other UK stakeholders, led by the Wellcome Trust, and with our European network, the Federation of European Academies of Medicine, to raise awareness of these research-related issues of the DPR, as the draft moves through the EU's legislative process. We have worked with these partners to publish a number of joint documents and positions, including a joint statement that has been supported by over 80 research organisations from the UK and across Europe.¹

¹ For more information: <http://www.acmedsci.ac.uk/policy/policy-projects/european-data-protection-regulation/>