



## **Ministry of Justice Call for Evidence on the Review of the Balance of Competences between the United Kingdom and the European Union: Information Rights**

Response from the British Heart Foundation  
June 2014

The British Heart Foundation (BHF) is the nation's leading heart charity. We are working to achieve our vision of a world in which people do not die prematurely or suffer from cardiovascular disease. In the fight for every heartbeat we fund ground breaking medical research, provide support and care to people living with cardiovascular disease and advocate for change.

### **BHF position on patient data**

Access to patient data is essential for medical research and, ultimately, for saving lives. The information held about patients in their medical records can be used to research the causes of disease, monitor survival rates, study the effectiveness of treatments and interventions, and identify appropriate participants for clinical trials. In other words, patient data hold the key to medical progress.

Some research in the social sciences also depends on access to personal data and the statistics derived from personal data, for example studying whether government policies have been effective and how they could be improved. Increasingly researchers are seeking to link together administrative information about one individual across a range of sectors – for example health, education and welfare – to build a better picture how these complex interactions affect our lives and wellbeing.

We agree that protecting privacy is crucial. The Data Protection Regulation must strike the right balance between protecting personal data whilst enabling life-saving research.

Due to our interest in this issue, we would like to respond to Question 4 from this Call for Evidence:

### **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?**

If implemented the European Parliament's amendments to Articles 81 and 83 would seriously impact on scientific research in the UK, including health research and the social sciences. The European Parliament position that emerged from amendments made by the LIBE committee is harmful and would make much research involving personal data at worst illegal, and at best unworkable.

The original draft Regulation proposed by the European Commission struck a crucial balance, setting out a proportionate mechanism for protecting privacy, whilst enabling health and scientific research to continue. It included a requirement for specific and explicit consent for the use of personal data concerning health, but provided an exemption from consent for research, subject to certain safeguards in Article 83.

The LIBE Committee's amendments to Articles 81 and 83 – now adopted by the European Parliament – very significantly reduce the scope of the exemption for research. For example, the use of personal data concerning health in research without specific consent would be prohibited or become very difficult in practice.

Consent is a crucial ethical principle and researchers must seek consent or use anonymous data where possible. However, it is not always feasible to seek consent, particularly where it is required to be specific and explicit. Where this type of research does take place, it is subject to ethical approval and strict confidentiality safeguards, and the identity of individuals is often masked.

**If implemented, the European Parliament's amendments 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.**

We hope that the position of the European Council and subsequent trialogue talks can recalibrate the balance between protecting privacy and enabling research that has been lost in the Parliament's amendments.

We hope our comments are useful. For more information on our position on the European Data Protection Regulation, please see the [Joint Statement](#) which we are signed up to with other European non-commercial research organisations and academics.

If you would like to discuss our comments further please contact Jennifer Boon, Policy Manager, Research and Prevention, on [boonj@bhf.org.uk](mailto:boonj@bhf.org.uk) or 0207 554 1117.