

Ministry of Justice
102 Petty France
London
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By email: informationrightsBOC@justice.gsi.gov.uk

23 June 2014

Re: Parkinson's UK Response to the Ministry of Justice call for evidence on the review of the balance of competences between the United Kingdom and the European Union: Information rights

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 holds the key to medical progress.

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 Committee on Civil Liberties, Justice and Home Affairs (LIBE) 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.

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Consent is a crucial ethical principle and researchers will 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, as this has been lost in the Parliament's amendments.

The following gives an example of a Parkinson's study that would be severely impacted by the EU Data Protection Regulation:

Tracking Parkinson's: Requirement to gain specific consent could stop largest ever Parkinson's study

Tracking Parkinson's is the world's largest ever in-depth study of people with Parkinson's. It is a five year project which aims to speed up the search for a cure by finding 'biomarkers', many of which circulate in the blood. Participants complete questionnaires, donate blood samples and have their Parkinson's symptoms carefully monitored at regular hospital appointments and give broad consent for this data to be shared with researchers. The information and samples collected in the study are made available to researchers studying Parkinson's all over the world free of charge.

This study would become unworkable under the LIBE committee's amendments since the form of consent is very narrow.

We hope our comments are useful. For more information on our position on the use of patient data for medical research, please see the Parkinson's UK position statement.¹

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.²

About Parkinson's

Parkinson's is a progressive neurological disorder for which there is currently no cure. It is associated with the death of nerve cells in the mid-brain which results in the loss of the chemical messenger dopamine. This affects learned voluntary movements such as walking, talking, writing and swallowing.

As the condition progresses it impacts on all aspects of the person's life and the lives of those around them.

¹ <http://www.parkinsons.org.uk/content/patient-data-policy-statement>

² http://www.wellcome.ac.uk/stellent/groups/corporatesite/@policy_communications/documents/web_document/WTP055584.pdf

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As well as the symptoms that affect movement, people with Parkinson's can find that other issues, such as tiredness, pain, depression and constipation, can have an impact on their day-to-day lives.

About Parkinson's UK

Every hour, someone in the UK is told they have Parkinson's. One in 20 is under the age of 40. There are approximately 127,000 people with Parkinson's in the UK.

We bring people with Parkinson's, their carers and families together via our network of local groups, our website and free confidential helpline. Specialist nurses, our supporters and staff provide information and training on every aspect of Parkinson's.

As the UK's Parkinson's support and research charity we're leading the work to find a cure, and we're closer than ever. We also campaign to change attitudes and demand better services.

Our work is totally dependent on donations.

For more information please contact Rachel Evans, **Clinical Research Policy and Campaigns Advisor**, revans@parkinsons.org.uk

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