



Breast Cancer Campaign's response to the Ministry of Justice's call for evidence on the Review of the Balance of Competences between the United Kingdom and the European Union: Information Rights

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About Breast Cancer Campaign

Breast Cancer Campaign specialises in funding innovative world-class research to understand how breast cancer develops, leading to improved diagnosis, treatment, prevention and cure. We only fund research into breast cancer and will support research at any centre of excellence in the UK or Ireland.

Breast Cancer Campaign currently funds 88 research grants throughout the UK and Ireland, worth just under £13 million. We also fund the Breast Cancer Campaign Tissue Bank at five sites across the UK, worth over £6.5 million.

Response to Consultation Questions

Breast Cancer Campaign welcomes the opportunity to respond to this call for evidence. This response focuses on Question 4 around the evidence of the impact of the proposed new EU Data Protection Regulation and includes the Breast Cancer Campaign Tissue Bank as an example.

The importance of patient data for research

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.

Some research in the social sciences also depends on access to personal data and the statistics derived from personal data, for example to study 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 of 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.

The impact of the proposed Data Protection Regulation on research

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 position adopted by the European Parliament following the LIBE committee's amendments 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 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.

Below is just one example of how vital research could be severely impacted by the proposed EU Data Protection Regulation:

The Breast Cancer Campaign Tissue Bank

About the Bank

The Tissue Bank is the first national UK resource for high-quality breast cancer tissue. It is a collaboration of five leading UK centres of excellence in breast cancer, working in partnership with the National Health Service. The Bank enables breast tissue samples, donated by people with breast cancer, to be stored safely and consistently and can be used by researchers anywhere in the UK and Ireland.

Accompanying the Bank is a unique bioinformatics portal providing a free and openly available tool to allow researchers anywhere to mine published data from a large range of breast cancer research and look for new patterns and links. This has the potential to open up new avenues of breast cancer research and to enable donated tissue to go further by preventing the duplication of research using tissue.

How the proposed Data Protection Regulation would impact on the Bank

To maximise the amount of research undertaken with the tissue it receives the Bank relies on broad consent from those who donate to it. If the scope of the Regulation's exemption for research were to remain as limited as proposed by the LIBE Committee, and there was a requirement to gain specific consent from donors every time their tissue was needed in a new piece of research, this would make the Breast Cancer Campaign Tissue Bank unviable because it would:

1. Increase the administrative cost and complexity of the consent process and hence the Bank itself
2. Potentially discourage donations of breast tissue, as donors may not wish to be contacted on numerous occasions when they may be receiving or recovering from breast cancer treatment.

The outcome of this would be to hinder the ability of researchers in the UK to identify a cure for breast cancer and help save the lives of the 12,000 women who still die of the disease every year in the UK.

Conclusion

We hope that the position of the European Council and subsequent dialogue talks can recalibrate the balance between protecting privacy and enabling research that has been lost in the Parliament's amendments and that our comments in response to this consultation 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.¹

If you would like to discuss our comments further please contact:

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¹ http://www.cancerresearchuk.org/sites/default/files/libe_report_joint_statement_january_2014.pdf