

**RCUK submission 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**

**Introduction**

1. Research Councils UK is a strategic partnership set up to champion research supported by the seven UK Research Councils. RCUK was established in 2002 to enable the Councils to work together more effectively to enhance the overall impact and effectiveness of their research, training and innovation activities, contributing to the delivery of the Government's objectives for science and innovation. Further details are available at [www.rcuk.ac.uk](http://www.rcuk.ac.uk)
2. This evidence is submitted by RCUK and represents its independent views. It does not include, or necessarily reflect the views of the Knowledge and Innovation Group in the Department for Business, Innovation and Skills (BIS). The submission is made on behalf of the following Councils:
  - Arts and Humanities Research Council (AHRC)
  - Biotechnology and Biological Sciences Research Council (BBSRC)
  - Engineering and Physical Sciences Research Council (EPSRC)
  - Economic and Social Research Council (ESRC)
  - Medical Research Council (MRC)
  - Natural Environment Research Council (NERC)
  - Science and Technology Facilities Council (STFC)
3. RCUK funding for research involving personal data includes investments in research programmes and infrastructure which have led to positive changes in clinical practice and informed policy in areas such as education, employment, housing, health and crime reduction. The UK holds a world leading position in public health research using longitudinal cohorts supported by the Research Councils such as the UK Biobank and the Life Study which will start recruiting a new birth cohort this year. Recent RCUK investments in areas including informatics, e-health research and the Administrative Data Research Network (ADRN) aim to enhance the UK's potential further to become a world leader in the use of routine health and administrative datasets for research.
4. RCUK welcomes the opportunity to contribute to this call for evidence. We believe that the amendments to the European General Data Protection Regulation (DPR) adopted earlier this year by the European Parliament are of serious concern for research across Europe and internationally. If implemented as amended the DPR would be extremely detrimental to social, economic and health policy and practice, in the UK and elsewhere in Europe. Due to our interest in this issue, we would like to respond to Question 4 from this Call for Evidence. This submission focuses primarily on the medical, biological and social sciences and draws on case studies from BBSRC, ESRC and MRC as areas where the DPR will have the most immediate impact. However, as we move to a more interdisciplinary and challenge based research environment we believe the DPR has the potential to affect research and investments in a wider range of areas supported by the research councils.

## **The use of personal data in RCUK funded research**

5. RCUK believe that the amendments to the European General Data Protection Regulation (DPR) adopted earlier this year by the European Parliament are not fit for the purpose of medical, biological and social science research. If ratified, the regulation would reduce the possibility of policy relevant research, which could have a serious negative impact on the lives of citizens across Europe. The proposed amendments would also prevent innovative research, due to the demand to obtain explicit consent (the type of research to be carried out is frequently not known in advance).
6. Access to personal data is essential for many areas of research which increases our understanding of health and society and ultimately saves and improves lives. Information held about patients in their medical records is used to research the causes of disease, monitor survival rates, study the effectiveness of treatments and interventions, and identify appropriate participants for research studies, cohorts and clinical trials. Research in the social sciences 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 such as health, education and welfare – to build a better picture of how these complex interactions affect our lives and wellbeing.
7. The UK has proportionate and robust systems to protect individual privacy, while allowing valuable health and social science research using personal data to go ahead. Consent is a crucial ethical principle and researchers will seek consent or use anonymous data where possible however the UK framework allows the use of data without consent in specific circumstances and in well governed environments, for instance through the Confidentiality Advisory Committee process for access to health records without consent. The information and discussions relating to the consent process explain the proposed uses of data, risks of identification and steps to mitigate risk. However, robust governance and ethics review are also essential in providing a high assurance of privacy, confidentiality and respect for data.
8. If implemented as proposed by the European Parliament the DPR would allow only a very narrow exemption from consent for the use of personal data in research. This would be highly damaging. The amendments represent a significant backward step from the Commission's original proposal and fail to recognise the enormous public benefit to be gained from responsible academic research using personal data. In contrast, the UK Government and Information Commissioner's Office have recognised that privacy and trust can be delivered via excellent governance. Such systems have been further clarified and strengthened through the work of Dame Fiona Caldicott for the Department of Health, and the Administrative Data Taskforce (ADT). New infrastructure such as the Administrative Research Data Network (ADRN) has the highest level of independence and public scrutiny as it reports to UK Parliaments via the UK Statistics Authority Board, which the ADRN Board is accountable to.
9. The Data Protection Regulation must strike the right balance between protecting personal data whilst enabling high quality research. The European Parliament's amendments would render the current UK system at worst illegal and at best unworkable.

**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?**

10. If implemented the European Parliament's amendments to Articles 81 and 83 would have serious negative impact on scientific research in the UK, including health and social sciences research.
11. The original draft Regulation proposed by the European Commission set 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.
12. 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. If agreed at the next stage of consideration this would mean the specific, explicit consent would be required for almost all processing of personal data for research. The use of personal data in research without specific consent would be prohibited or become very difficult in practice and would effectively remove the research exemption from all but the highest priority public health areas, such as civil emergencies.
13. The over-emphasis on consent fails to take account of strict ethical approval processes and safeguards that apply to research using personal data where it is not always feasible to seek the specific, explicit consent proposed. Once adopted there will be limited scope for individual member states to interpret the Regulation for national implementation. We believe that the current route to approval of access to health records without consent through the Confidentiality Advisory Committee would not be legal, that individual projects using cohort data would need further specific consent (even if no further data collection or interventions are required) and that cohorts would need to be re-consented on a regular basis. These actions present significant risks of research bias and attrition of cohorts due to a failure to respond rather than a real disinclination to continue participation. The amendments would seriously hinder researchers' ability to analyse datasets that have been built up with large amounts of funding (for example, the 34 cohorts that comprise the majority of large scale population studies in the UK have a combined annual spend of £27.6m) over many years and make it impossible for researchers using anonymised data to gain consent.
14. The UK has an unparalleled collection of large scale cohorts which have provided insights into the determinants of health, wellbeing and disease and have transformed our understanding of the complex trends affecting UK society. Longitudinal studies and cohorts, such as those supported by the ESRC, MRC and BBSRC over many years, represent extremely powerful and cost-effective methods of investigating health and social science research questions. The MRC's recent strategic review, *Maximising the value of UK population cohort studies*<sup>1</sup>, found that there are currently around 2.2 million UK volunteers (1 in 30 people) participating in cohorts for health and social science research. Many cohort participants have given broad and durable consent for data about them from different sources – such as health data and administrative data from other Government departments – to be linked together to create powerful research resources. However, this broad consent is not likely to be acceptable under the European Parliament's amendments. This will jeopardise

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<sup>1</sup> <http://www.mrc.ac.uk/news-events/publications/maximising-the-value-of-uk-population-cohorts/>

research which aims to inform policy, such as studies which aim to identify risk factors and preventive strategies for diseases including Alzheimer's which forms a key part of the UK Government's Dementia strategy, and will also restrict the ability to use longitudinal research data to inform the development of policy interventions, such promoting general well-being of the UK population.

15. The European Parliament's position also does not recognise that de-identified or pseudonymised data in research are expected to be used within a very robust governance system with strict organisational, legal and technological safeguards to protect privacy. A strict reading means that data would be considered within the scope of the Regulation even where data are double coded by separate trusted third parties and researchers do not have access to codes to re-identify individuals.
16. The DPR presents significant risks to major European and national investments in genetics, cohort studies, biobanks, disease registries and the use of routinely collected data, new and existing, and associated progress towards understanding society, health, and disease that delivers real benefit. The DPR also contributes to uncertainty around how researchers can respond to the new opportunities that exist in the 'big data' era to extract insights from large and complex datasets; including many valuable datasets where it is often not feasible to gain specific consent. Taking these new opportunities will help us to understand the relationship between genetics and other factors in health and disease and determine important molecular pathways for the targeting of therapeutics.
17. Recent UK Government commitments for big data infrastructure and development reflect the enormous potential of big data for the economy, in creating opportunities for driving research and development, increasing productivity and transforming public and private sector organisations. Of the total £189 million earmarked, £64m has been allocated to establish the Big Data Network, the first phase of which is the Administrative Data Research Network. An investment that aims to unlock the research potential of de-identified administrative data routinely collected by UK government departments and agencies. Last year, the ESRC and Office for National Statistics commissioned a series of dialogues across the UK to understand better how people view using administrative data for research<sup>2</sup>. The potential of big data is recognised internationally with the US Government recently releasing a statement<sup>3</sup> on their intention to take the international lead in the use of big data for research purposes, for the benefit of science and society, by using practical privacy-protecting technologies, and also focusing any policy-making on the use of data, rather than the collection and analysis of data. Given this approach the European Union risks losing its global position in scientific inquiry if the European Parliament's proposed amendments to the DPR are enacted.
18. Researchers and scientists in the UK and across Europe are unleashing the power of personal datasets, thereby advancing scientific discovery and addressing issues that affect almost every aspect of our lives. Social science research has demonstrated: the link between unemployment and ill-health; the link between smoking in pregnancy and low birth weight; and has identified the long-term socio-economic benefits to children who are breastfed. Restricting the use of personal data for these and many other types of study would limit our ability to ensure UK and European policy-making is informed by the most robust evidence base.

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<sup>2</sup> <http://www.esrc.ac.uk/public-engagement/public-dialogues.aspx>

<sup>3</sup> <http://www.whitehouse.gov/blog/2014/05/01/pcast-releases-report-big-data-and-privacy>

19. A clear framework for the governance of data relating to people which protects privacy, retains public confidence in research and the high-level of public participation and support for the use of personal data in research while facilitating research opportunities is essential to support research effectively.

**RCUK supported cohorts and longitudinal studies that may be at risk:**

- Understanding Society<sup>4</sup> is the largest household panel survey in the world and builds on 18 years of the British Household Panel Survey. A unique and valuable academic study, it captures important information every year about the social and economic circumstances and attitudes of people living in 40,000 UK households. This resource has transformed our understanding of the complex trends affecting UK society, and informed long-term policy making in many areas of government.
- The Millennium Cohort Study (MCS)<sup>5</sup> follows the lives of around 19,000 children born in the UK in 2000-01. The study has been tracking the Millennium children through their early childhood years and plans to follow them into adulthood. It collects information on the children's siblings and parents. MCS's field of enquiry covers such diverse topics as parenting: childcare: school choice; child behaviour and cognitive development; child and parental health; parents' employment and education; income and poverty; housing, neighbourhood and residential mobility; and social capital and ethnicity. *(ESRC funding)*
- The Life Study<sup>6</sup>, is a new and very important research study that will involve more than 80,000 babies born between 2014 and 2018 – and their families – from across the UK. Life Study will collect information about these babies over their early lives and childhoods and into adult life. This will help us understand how early life experiences shape health and wellbeing later on. *(ESRC and MRC funded)*
- The Centre for Cognitive Ageing & Cognitive Epidemiology (CCACE)<sup>7</sup> in Edinburgh maintains and develops the unique long-term human cohort studies assembled in Scotland as new national resources. The Lothian Birth Cohorts provide information on intelligence and cognitive performance across the life-course, including data on reasoning, memory, speed of thinking as well as wider aspects of fitness and health. Research using data from the cohorts has helped to provide significant insights into cognitive decline. For example, a recent study showed that speaking a second language slows the decline of thinking skills in later life. *(BBSRC and MRC funded through the Lifelong Health and Wellbeing Initiative)*
- The Cambridge Centre for Ageing and Neuroscience<sup>8</sup> studies how age-related changes in brain structure and function relate to patterns of preserved and declining cognitive function. During the first two years of the project the focus has been on building a population-representative cohort of 3,000 participants across ages 18-88. This is a complex and resource-intensive process, but one which will create a unique cohort of healthy adults across the lifespan with combined neural, cognitive, and epidemiological assessment. The cohort will provide the basis for examining longitudinal trends in both healthy ageing and the precursors to cognitive decline. *(BBSRC funded)*

<sup>4</sup> [www.understandingsociety.ac.uk](http://www.understandingsociety.ac.uk)

<sup>5</sup> <http://www.cls.ioe.ac.uk/page.aspx?&siteid=851&siteid=Welcome+to+the+Millennium+Cohort+Study>

<sup>6</sup> [www.lifestudy.ac.uk](http://www.lifestudy.ac.uk)

<sup>7</sup> <http://www.ccace.ed.ac.uk>

<sup>8</sup> <http://www.cam-can.com>

- ### Policy Impact of RCUK supported studies:

- <sup>9</sup> <https://www.understandingsociety.ac.uk/2013/06/04/grandparents-throw-squeezed-families-a-life-line>

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<sup>11</sup> <http://www.demos.co.uk/poverty/toolkit>

<sup>12</sup> <http://sd.defra.gov.uk/2013/07/would-you-be-happier-living-in-a-greener-urban-area/>

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<sup>14</sup> [https://www.gov.uk/government/uploads/system/uploads/attachment\\_data/file/177031/CM-8061.pdf](https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/177031/CM-8061.pdf)

- Researchers at the University of Exeter have made extensive use of the British Household Panel Survey (and Understanding Society) to investigate relationships between the environment and health and wellbeing – particularly looking at greenspace and bluespace and psychological wellbeing<sup>12</sup> and have great relevance to UK and European environmental and public health policy.
- Research findings from birth cohorts, like the MCS, have been used extensively to inform policy in a wide range of areas:
  - Evidence from the 1958, 1970 British Cohort and MCS was cited by the Welsh Government in its first Early Years and Childcare Plan. The 10-year plan highlights findings from the studies that show factors such as a mother's health during pregnancy, birthweight, parents' education and employment, housing and socio-economic circumstances have a lasting effect on children's cognitive, social and behavioural development<sup>13</sup>.
  - The influential 1999 Social Exclusion Unit report, *Bridging the Gap*, which led to the creation of the Connexions service, drew on the 1970 cohort. The research showed how prolonged periods of being out of education, employment or training after leaving school have long-term negative consequences for employment and mental health.
  - Alongside the Social Mobility Strategy, the Department for Work and Pensions and the Department for Education also published a new child poverty strategy '*A New Approach to Child Poverty: Tackling the Causes of Disadvantage and Transforming Families' Lives*'. This also drew on research based on the British cohort studies, particularly relating to the role of early intervention in improving how children do at school<sup>14</sup>.
  - The MCS has made important contributions to the national evaluations of two major programmes, Sure Start and the Children's Fund, and has been the subject of several Centre for Longitudinal Studies (CLS) reports for policy-makers – on child development; the social and demographic profile of rural areas and childcare. The Welsh Assembly Government commissioned a report from the MCS team on young motherhood, while a report for the Scottish Executive assessed the implications of the age 3 survey results for Scotland. Another analysis of the social profile of births in Scotland based on the age 9 months MCS survey contributed to the debate about population decline in that country.
- Researchers based at the University of Surrey, and funded by Surrey Police, ESRC, and the Home Office, developed and piloted the on 'Neighbourhood Policing' (NP) approach to policing, implemented demonstrator projects, and evaluated them. Repeat interviews were conducted with sample members over a period of time to assess whether effects of NP were enduring, and data from these was used to inform survey instruments administered using a longitudinal design. NP was then adopted at national level across the UK. The NP model led to positive impact on self-reported victimisation, and measurable, sustained gains in public confidence in policing.

**Major cross EU-initiatives that would be put at risk include:**

- European Prospective Investigation into Cancer and Nutrition (EPIC), the largest study of diet and health ever undertaken, involving half a million European citizens, which uses broad consent from participants to allow researchers to access relevant data through rigorous governance arrangements.
- The European Social Survey (ESS) measures the attitudes, beliefs and behaviour patterns of diverse populations in more than thirty nations. Recently awarded European Research Infrastructure Centre status, the ESS plays a pivotal role in informing European governance and academic debate, providing reliable and durable measures that are central to our understanding of modern Europe and of change within it and to developing responsive social and economic policy.

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

For more information on our position on the European Data Protection Regulation, please see the Joint Statement which we issued with other European non-commercial research organisations and academics.<sup>15</sup>

**Contact**

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

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<sup>15</sup> [http://www.cancerresearchuk.org/sites/default/files/libe\\_report\\_joint\\_statement\\_january\\_2014.pdf](http://www.cancerresearchuk.org/sites/default/files/libe_report_joint_statement_january_2014.pdf)