

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 by the Wellcome Trust

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Key Points

- The UK's implementation of the Data Protection Directive (1995) allows world-leading health research with personal data to take place in the UK. Despite this, the detail of the Data Protection Act and complexity of the legal framework for the use of personal data in the UK have led to delays in studies.
- The Commission's proposal for a Data Protection Regulation provides vital derogations for the processing of personal data for scientific research under certain conditions. However, the European Parliament's amendments to Articles 81 and 83 of the Regulation present a very serious concern as these would tightly restrict the processing of data concerning health for research and would make many studies impossible or unworkable.
- The UK Government must seek to ensure the derogations for research are protected in the Council's text and support the Council Presidency to oppose the European Parliament's position.

INTRODUCTION

1. We welcome the opportunity to respond to this call for evidence. Our response focuses on Data Protection and specifically the impact of the Data Protection framework on the processing of personal data for research. It is vital that the UK and EU can establish a regulatory framework that balances the rights and interests of individuals with the societal benefits of research using personal data.

QUESTION 1

What evidence is there that the EU's competence and the way it has been used (principally the Data Protection Directive) has been advantageous or disadvantageous to individuals, business, the public sector and any other groups in the UK?

2. As implemented in the UK through the Data Protection Act (1998) (DPA), the Data Protection Directive (1995) (DPD/ Directive 95/46) allows world-leading health research using personal data to take place in the UK. The UK's interpretation of the DPD has found an appropriate balance in permitting health research while protecting the interests of individuals. This approach is supported by important safeguards outside the DPA, including approval by a Research Ethics Committee and, where required, the Confidentiality Advisory Group.

3. With respect to research, Member States have interpreted and implemented the DPD in different ways. For example, there is variation across countries in the extent of exemptions from consent for the use of personal data in medical research.¹ The UK has taken a favourable interpretation of the DPD for research, for example the inclusion of “medical research” in the definition of “medical purposes” facilitates the use of health data in research.² Other countries have also interpreted the DPD to deliver a positive environment for health research using personal data, for example the Danish Government says “Danish law provides – in accordance with Directive 95/46 – an independent legal basis for processing of personal data for scientific purposes.” The differences in interpretation across Member States make it difficult to assess the impact of the DPD itself, as opposed to the specific interpretation taken in the DPA.
4. While the UK’s interpretation of the DPD is largely positive for research at a high level, the complexity and detail of the DPA has caused problems for many sectors, including the research community. The research community has found the DPA difficult to interpret, for example how the definition of ‘clinical care team’ should be interpreted and how the scope relates to robustly pseudonymised data. The lack of clarity in the current UK Data Protection Act has contributed to a risk-averse culture among those sharing and using data for research. This has led to delays to research that would benefit the public.³
5. Further, the wider privacy framework in the UK is highly complex and includes the common law duty of confidentiality and associated exemptions, in addition to the DPA. Together the DPA and complexity of the landscape as a whole leads to confusion and misinterpretation. The *Data Sharing Review*⁴ of the framework for the use of personal information in the public and private sectors concluded “it is clear that the framework as it stands is deeply confusing and that many practitioners who make decisions on a daily basis about whether or not to share personal information do so in a climate of considerable uncertainty.” However, the available evidence does not reveal the extent to which the DPD and its implementation through the DPA have directly contributed to this uncertainty and complexity in the landscape, or whether a comparable UK law could have avoided these issues.

QUESTION 3

What evidence is there that the EU’s competence and the way it has been used (principally the Data Protection Directive) is meeting the challenges posed by the increasing international flow of data, technological developments, and the growth of online commerce and social networks.

6. Much has changed since the introduction of both the DPD and the DPA and it is important that the regulatory framework keeps pace with advances in technology and developments in the potential uses of data. For example, capability in genetic

¹ Privacy in Research Ethics and Law (PRIVIREAL) study <http://www.privireal.org/content/dp/>

² Data Protection Act (1998) Sch. 3 para. 8(2)

³ Academy of Medical Sciences (2011) [A New Pathway for the Regulation and Governance of Health Research](#)

⁴ Richard Thomas and Mark Walport (2008) [Data Sharing Review](#)

sequencing and the use of genetic data has grown hugely since 1995, when the Human Genome Project – which sought to sequence the full human genetic code for the first time – was still in its early stages. In 2010 the European Commission recognised that “rapid technological developments and globalisation have... brought new challenges for the protection of personal data.”⁵ However, in the four years since, only limited progress has been made towards the new Regulation intended to address these challenges. The EU legislative process rightly includes time for consultation with stakeholders and for informed consideration of the text in Parliament and Council, but the slow nature of the process means that it lacks agility to respond to the changing environment. It is therefore particularly important that the new regulatory framework is future-proofed so that it can adapt to rapid technological developments.

QUESTION 4

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

7. The Commission’s proposal for a Regulation would establish a proportionate framework for research. However, the European Parliament’s amendments to Articles 81 and 83 of the Data Protection Regulation would severely restrict the use of personal data concerning health in research, making important studies impossible or unworkable. An open letter from European research organisations published in *The Times* and *Europolitics* earlier in 2014 said that the amendments pose “a significant risk to millions of euros of investment in scientific infrastructure, including cancer registries, cohort studies and biobanks.”⁶
8. The following sections set out our position on the Commission’s proposal and the Parliament’s amendments, and consider how the latter can be opposed through Council.

Commission’s proposal for a Data Protection Regulation

9. The Commission’s proposal for a Data Protection Regulation (DPR) provides a number of derogations from particular requirements for the use of ‘personal data’ for scientific research, providing that personal data is processed in accordance with the conditions set out in Article 83. These derogations do not exempt research studies from all the requirements set out in the DPR. We support this approach since it provides a proportionate framework that balances the facilitation of research with the protection of the interests of research participants.

⁵ European Commission (2010) [A comprehensive approach on personal data protection in the European Union](#)

⁶ [Open letter re: amendments to EU Data Protection Regulation](#) (2014)

10. However, there are a number of issues around Article 83 and the associated derogations that would benefit from clarification to better reflect the intent of the clauses, particularly the following:
 - Lawfulness of processing: the relationship between Articles 6(1), 6(2) and 83(1) should be clarified to provide legal certainty on whether scientific research is a legal basis in its own right, subject to the conditions and safeguards in Article 83(1).
 - Processing of personal data concerning health: it should be clarified that the reference to Article 83 (processing for historical, statistical and scientific research purposes) within Article 81 (processing of personal data concerning health) is intended to link the two sections, rather than to impose an additional condition.
11. Essential safeguards exist to protect research participants beyond data protection law, such as Research Ethics Committee approval. The DPR could be strengthened to clarify the important role of these existing safeguards, such as project approval by an independent ethics committee.
12. Research is an international activity and would benefit from clear and harmonised rules that facilitate research across Member States. A Regulation that strikes the right balance in promoting research while protecting individual interests has the potential deliver this and increase consistency across Member States. However, given the current differences in Member State law (see paragraph 3), we recognise the difficulties of agreeing a harmonised text on research and consider that harmonisation should not be delivered at the cost of significantly weakening the Commission's provisions.

European Parliament amendments to the Data Protection Regulation

13. The European Parliament's amendments to Articles 81 and 83 very significantly reduce the scope of the exemption from consent for research, particularly for data concerning health. These amendments would affect research in the following ways:
 - Pseudonymous data concerning health – where an individual's identity is masked to protect privacy – could only be used without specific consent where research is in the "high public interests" and "cannot possibly be carried out otherwise". This would make it very difficult, if not impossible in practice, to use pseudonymised data concerning health without specific consent.
 - The use of identifiable personal data concerning health in scientific research without specific consent would be prohibited. Researchers only use identifiable data without consent where other approaches are not practicable and this is currently only allowed subject to ethical approval and strict confidentiality safeguards. Sometimes researchers need details such as age, postcode and information on a health condition that together could disclose the identity of an individual, but the study would not be possible without it.
14. The disproportionate restrictions on the use of personal data concerning health proposed by the European Parliament fail to take account of the fact that this research is subject to ethical approval and strict confidentiality safeguards. The amendments also do not

reflect the practical reality of research, which often relies on a 'broad consent' model, which is not compatible with the requirement for consent for "specific and similar researches". A detailed analysis is available in a joint statement from over 90 research and academic organisations across the EU.⁷

15. The amendments will put at risk significant public and charity investments in genetics, cohort studies and the use of routinely collected data, such as:

- UK Biobank - a major national health resource that aims to improve the prevention, diagnosis and treatment of a wide range of serious and life-threatening illnesses. Half a million people in the UK have given broad consent for their data and samples to be used for health-related research. The investment of over £80 million and the altruistic contribution of participants could be wasted if the Parliament's amendments are adopted since the very narrow exemption from consent for the use of pseudonymous data is likely to make the resource unworkable.
- The European Prospective Investigation into Cancer and Nutrition (EPIC), the largest study of diet and health ever undertaken, would be similarly affected. EPIC involves over half a million European citizens and uses broad consent from participants to allow researchers to access relevant data through rigorous governance arrangements.
- The Clinical Practice Research Datalink (CPRD) in England, the Scottish Health Informatics Programme (SHIP) and the Secure Anonymised Information Linkage (SAIL) in Wales have benefited from millions of pounds of public and charity investment to create state of the art facilities for the secure use of NHS data in research for health benefit. Since these resources would rely on processing pseudonymised health data, they would become difficult or impossible to operate in practice if the Parliament's amendments are implemented.
- In England and Wales, legislation provides an exemption from a common law requirement for consent for the use of identifiable confidential medical information collected through the NHS. In 2012, around 70 research studies were granted use of the exemption. These studies also required approval by a Research Ethics Committee. It would not be possible to conduct these studies under the Parliament's amendments to Articles 81 and 83.

UK and Council of the European Union position

16. In negotiations on the Council position, the UK Government must ensure the research derogations in the Commission's text are protected. This will create a strong negotiating position to oppose the European Parliament's amendments in triilogue discussions. In particular:

⁷ Position of non-commercial research organisations and academics (2014) [Protecting health and scientific research in the Data Protection Regulation](#)

- Articles 6(2), 81 and 83 should be maintained to achieve a clear, practical and proportionate legal basis for research that does not rely on specific consent.
 - Article 6(4) and Recital 40 should be maintained to ensure that scientific research can be considered a 'not incompatible' purpose for the secondary processing of personal data.
17. As noted above, Member States have taken different interpretations of the DPD from a research perspective. We recognise that this may make it difficult to achieve agreement on the research provisions in the Regulation. However, it is vital that the research provisions in the Commission's text are not diluted because of this, since this would weaken the research environment in countries – including the UK – that have a strong track record in the safe and secure use of personal data in research.
18. We are pleased that the Department of Health and Department of Business, Innovation and Skills have been working with the Ministry of Justice towards achieving a positive outcome for research. We hope this collaboration will continue.

The Wellcome Trust is a global charitable foundation dedicated to achieving extraordinary improvements in human and animal health. We support the brightest minds in biomedical research and the medical humanities. Our breadth of support includes public engagement, education and the application of research to improve health. We are independent of both political and commercial interests.