

DELEGATED POWERS AND REGULATORY REFORM COMMITTEE

DATA PROTECTION BILL

Supplementary Memorandum by the Department for Digital, Culture, Media and Sport

Introduction

1. This supplementary memorandum has been prepared for the Delegated Powers and Regulatory Reform Committee by the Department for Digital, Culture, Media and Sport (“DCMS”).
2. It identifies an additional provision proposed for addition to the Data Protection Bill (the “**Bill**”) which confers powers to make delegated legislation and explains why the power has been proposed and the nature of, and reason for, the procedure selected.
3. DCMS have considered this addition to the Bill as set out below and is satisfied that it is necessary and justified.

CLAUSE 18: PROCESSING FOR ARCHIVING, RESEARCH AND STATISTICAL PURPOSES: SAFEGUARDS

New subsection (4) of clause 18: Power to amend definition of ‘approved medical research’

<i>Power conferred on:</i>	<i>Secretary of State</i>
<i>Power exercisable by:</i>	<i>Regulations made by statutory instrument</i>
<i>Parliamentary Procedure:</i>	<i>Affirmative resolution procedure</i>

Context and purpose

4. Article 89(1) of the General Data Protection Regulation (“GDPR”) permits the processing of special categories of data for archiving in the public interest, scientific and historical research purposes or statistical purposes, providing that the data controller puts appropriate technical and organisational measures

(such as the use of pseudonymisation) in place to keep the data safe and secure.

5. Clause 18(2) of the Bill supplements these safeguards by making it clear that processing for such purposes does not meet the requirements of Article 89(1) if it causes substantial damage or distress or leads to measures or decisions being taken about data subjects. During Lords Committee stages of the Bill, concerns were raised by Lord Patel and others that some types of medical research could be impeded by the current drafting of clause 18. He explained that clinical trials, interventional research and comparative research studies may all rely to some degree on measures or decisions being taken about data subjects without their explicit consent: “the research community has developed a system of robust and proportionate safeguards for these situations, to ensure that research on important topics can be undertaken using personal data where consent is not possible while protecting the research subjects... [including requiring] a positive opinion from a research ethics committee to be eligible.” (*Hansard*, vol. 785, col. 1252).
6. It was not the government’s intention to impede pioneering medical research with obvious benefits for society as a whole. The government has therefore tabled an amendment to clause 18 which would dis-apply the safeguard in clause 18(2)(a) where medical research has been approved by one of the bodies listed in the definition of “approved medical research” in new subsection (3). Other safeguards are retained (subject to minor amendment). For example, research cannot be undertaken if it would cause substantial damage or substantial distress to a data subject.
7. The amendment also contains a new regulation-making power new subsection (4) so that the Secretary of State can amend the definition of “approved medical research” and other related provisions in subsection (3) (for example, definitions of terms used in the definition of “approved medical research”).

Justification for taking the power

8. Without a power to amend the definition of approved medical research through secondary legislation it would be necessary to make further primary legislation to amend the list of bodies that are capable of approving medical research for the purposes of the new exception. If a new body were established, secondary legislation would be the most effective way of ensuring there was no undue delay in allowing that body to approve processing of personal data for medical research purposes. Although the government does not envisage the power would be used very often, governance arrangements can change from time to time – for example, UK Research and Innovation was established by the Higher Education and Research Act 2017 and, in April 2018, will replace a number of separate Research Councils that were created under the Science and Technology Act 1965. If clause 18(3) could not be amended via secondary legislation, it would potentially delay new bodies granting approval for potentially pioneering and/or life-saving research.

Justification for the procedure

9. By virtue of new subsection (5) of clause 18, the affirmative resolution procedure will apply to regulations made under new subsection (4). The affirmative procedure is considered appropriate given the Henry VIII nature of the power and the fact that regulations made under clause 18(4) relates to safeguards in respect of processing of personal data for scientific purposes.

Department for Digital, Media, Culture and Sport

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