Data Protection Team
Department for Culture, Media & Sport
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Dear Sirs

GDPR Call for Views

We welcome the Government's call for views on the implementation of derogations under the GDPR.

As a world leader in the collection, analysis, and interpretation of health data, with a large presence in the UK, QuintilesIMS fully supports the objective of ensuring a high level of the protection of personal data whilst enabling access to information that has been appropriately safeguarded.

Comprehensive health services research and the analysis of health care data allow the NHS and its partners to identify the deficits in patient care and treatment; it is also essential for assessing the impact of the Government's national health policy. Much of the UK's expertise in collecting and analysing data to evaluate the access to and delivery of healthcare resides in the private sector, involving private undertakings, such as QuintilesIMS.

The GDPR has recognised the importance of scientific and statistical research and reserves powers to Member States to permit data processing carried out without consent under appropriate conditions, including by private sector organisations. It is important that the UK takes this opportunity: reliance on consent would hinder important research where consent has not been obtained. For example the European Medicines Agency used de-identified but patient-level data, provided by QuintilesIMS, to identify an association with an increased risk of death in children prescribed codeine following tonsillectomies. The results of this analysis led to a revision of clinical guidelines for tonsillectomies.

We remain ready to provide any further input the Government requires on this topic.

Yours faithfully,

Theme 7: The UK should legislate to provide a specific legal basis to process sensitive data for statistical and scientific research

GDPR recognises, in Article 9(j) and Article 89(1) that organisations should be able to process sensitive personal data for the purposes of scientific and statistical research without explicit consent where appropriate safeguards are in place. For example, Recital 157 explains the important of registries, and the value of research that can draw on identifiable data over a large population. However, this has been left to Member States to legislate and implement in their jurisdiction.

If the UK does not implement legislation to take advantage of Article 9(j), this would require researchers to seek consent to conduct their studies. As set out in our letter, this could impede important research conducted by public and private sector organisations. For example, studies that can only use data from patients that are healthy or educated enough to give consent are, of course, biased towards such patients. Researchers call this effect "nonparticipation bias". Individuals that are perhaps most in need of help, but least able to give consent, are excluded from studies. By way of example, a study on breast cancer in 2015 found that individuals with low education or low income were less likely to participate. The study would have over-represented people who already have access to the best healthcare.

The UK already recognises the importance of statistical and scientific research in the Data Protection (Processing of Sensitive Personal Data) Order 2000, paragraph 9. The UK Government should take action again to ensure that researchers can continue to process data for their studies where this is subject to appropriate safeguards. The Order already contains safeguards, albeit that it also includes a requirement that data is processed in the substantial public interest, a legacy of the drafting of the Directive that is no longer necessary.

Proposed solution: in light of the GDPR's stricter rules on consent, and the specific recognition of research under Article 9(j), the UK should seek to re-implement an exemption such as paragraph 9 of the Order.

Beyond Brexit: Important that UK law reflects Article 11.

We understand that the Government is currently reflecting on how it will implement and retain various European laws in the Great Repeal Bill, and it has not publically announced how it will reflect the GDPR in law once the UK has left the European Union.

Article 11 of the GDPR means that, where a controller no longer needs to identify the data subject, they are not required to accept more information to permit re-identification and allow a data subject to exercise rights under Articles 15-20. This is very important for health research, where an obligation to obtain additional data in order to comply with data subject requests would undermine attempts to ensure that patients cannot be re-identified.

We understand that Article 11 is not a topic where the Government has called for views. However, QuintilesIMS is only able avoid a need for specific derogations to various subject rights on the basis that it seeks to rely on de-

identification techniques. It is paramount that the UK retains this important principle in its final legislation once it exits the European Union.

Proposed solution: Article 11 should be retained if the UK intends to effectively shadow legislate the GDPR in anticipation of Brexit. If the GDPR will be maintained through reference in the Great Repeal Bill, then Articles 11 must be included in that process.