Department for Culture, Media and Sport – Call for Views: GDPR Derogations

Response by health and research organisations

10 May 2017

KEY MESSAGES

- The Department of Culture, Media and Sport (DCMS) must ensure there are clear alternatives to consent to legitimise the processing of personal data for research. In addition to consent, it is essential to provide clear legal bases for processing personal data (Article 6) and processing sensitive personal data (Article 9) for research.
- DCMS must work with the Health Research Authority (HRA), Department of Health, the Information Commissioner's Office (ICO) and the devolved administrations to identify safeguards to meet the requirements of Article 89(1) and ensure that they are clear and understood by researchers.
- DCMS should provide derogations from the rights in Articles 15 and 16 as allowed for in Article 89(2). DCMS should also consider the possibility of providing a derogation for Article 13 where appropriate safeguards are met.
- DCMS should work with the HRA, Department of Health, ICO and the devolved administrations to provide sector-specific guidance for health research, including on legal bases, safeguards and derogations.
- Criminal sanctions should be introduced for the most serious and deliberate breaches of data protection, including for the unwarranted and unauthorised deliberate re-identification of data subjects from pseudonymised data.

General points

1. This response aims to provide recommendations for supporting health research in the UK. Wider issues affecting research, including Freedom of Expression (Article 85) and derogations for other types of research, statistical and archiving purposes (Article 89) are important and must be addressed, but are beyond the scope of this response.
2. 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 health research. This has prevented and

delayed research that would be in the public interest[1]. Implementing the General Data Protection Regulation is therefore an important opportunity to provide greater certainty and clarity for researchers, and to support work to build public trust in the use of health data in research. In addition to implementing the derogations discussed below, clear, definitive advice will be essential to support and inform researchers, funders and other stakeholders. As far as possible implementation – such as specifying safeguards – should rely on existing approaches.

3. Research often involves different types of personal data and takes place across disciplines, private and public sector organisations, and countries. However, across the UK, research disciplines and types of data, the law on the use of personal data in research is fragmented. While implementation of the GDPR may be able to rely on existing approaches in one sector, for example in health, it is important that the full spectrum of disciplines and data are considered to ensure no gaps are left. In the longer term, the Government should seek to create a more consistent and coherent approach for the use of all types of personal data across all research disciplines.

4. In addition, the devolved administrations have different approaches to confidentiality and DCMS must ensure that this is taken into account and does not become a barrier to beneficial data sharing between England, Wales, Scotland and Northern Ireland.

5. DCMS should also monitor how EU Member States chose to implement Article 89 and its associated derogations, to minimise as far as possible the burden on research projects taking place in more than one Member State.

Theme 2 – Sanctions

Recommendation: DCMS should introduce criminal sanctions for the most serious misuses of personal data, including unwarranted and unauthorised re-identification of data subjects from pseudonymised data (Article 58).

6. There is significant potential for harm from malicious misuse of personal data or re-identification of data subjects from pseudonymised data, which justifies an appropriately stringent deterrent[2].

7. At present, we do not believe that existing sanctions for misusing personal data or re-identifying data subjects are strong enough to reassure the public that malicious misuse or unauthorised and unwarranted deliberate re-identification would be treated as a crime. We suggest criminal sanctions should be introduced in the UK (Article 58) for the most serious misuses of personal data where there was deliberate intent. Criminal sanctions should cover deliberate re-identification of data subjects from pseudonymised data outside the scope of the General Data Protection Regulation.

8. To prevent criminal sanctions driving unnecessarily risk-averse behaviour, it is important that sanctions are proportionate and incorporated into a joined up approach that includes clarity on the legal bases for processing and derogations and clear, pragmatic guidance on the GDPR, its scope and sanctions.

[1] Academy of Medical Sciences – A new pathway for the regulation and governance of health research https://acmedsci.ac.uk/file-download/35208-newpathw.pdf
[2] Wellcome Trust – Response to House of Commons Science and Technology Committee: The Big Data Dilemma https://wellcome.ac.uk/sites/default/files/wtp059804.pdf

Theme 5 – Archiving and research

Recommendations:

DCMS must work with the Health Research Authority (HRA), Department of Health, the Information Commissioner's Office (ICO) and the devolved administrations to identify safeguards to meet the requirements of Article 89(1) and ensure that they are clear and understood by researchers.

DCMS must provide derogations for scientific research for Articles 15 and 16, in line with Article 89(2).

9. Article 89(1) requires "appropriate safeguards" to be put in place for processing for scientific research to benefit from special provisions in Articles 5, 9, 14, 17 and 21.

10. DCMS must determine whether safeguards in non-binding guidance are sufficient to meet the requirements of Article 89(1) and associated derogations, including Article 9(2)(j), or whether these safeguards must be in legislation or statutory guidance. If possible, specifying the appropriate safeguards in guidance rather than legislation would provide more flexibility to update these as technology changes.

11. As far as possible, the safeguards specified should not be new, but use current approaches such as Research Ethics Committee opinions and Section 251 approvals from the Confidentiality Advisory Group, which we consider to be sufficient to satisfy the requirements of Article 89(1).

12. Regardless of the safeguards and how they are specified, it is essential that researchers understand and are clear about what safeguards they need to apply in order to benefit from the derogations. Sector specific guidance on the safeguards – produced by the HRA in consultation with DCMS, ICO, Department of Health and the devolved administrations – is essential to support research. It may be helpful to pursue Code of Conduct status under Article 40 for guidance produced by regulators or the research community.

13. Article 89(2) allows the UK to provide derogations from the rights in Articles 15, 16, 18 and 21, subject to the conditions and safeguards of Article 89(1). Our response to Theme 13 outlines our rationale for which derogations from data subject rights we believe are necessary to support UK research. In brief, we request DCMS to provide derogations for Article 15 and Article 16. We do not seek derogations for Articles 18 and 21.

Theme 6 – Third Country Transfers

14. International transfers of data are important for research in academia and industry. It is important that robust mechanisms, that provide legal certainty and consistency, are in place to support this. This must be provided through Articles 45, 46 and 49, both before and after Brexit.

Theme 7 – Sensitive personal data and exceptions

Recommendations:
DCMS must ensure there is a clear alternative to consent as the legal basis for processing of sensitive personal data for health research (Article 9(2)(j)). DCMS should work with the HRA, the Department of Health and the devolved administrations to identify a solution. Options may include, but are not limited to, using legislation equivalent to the Data Protection (Processing of Sensitive Personal Data) Order 2000; relying the Control of Patient Information regulations; or relying on meeting the common law of confidentiality

15. In some situations it is not practical or possible to obtain consent for the use of personal data in research. For example, seeking consent may introduce bias in the results, increasing the chance of researchers reaching the wrong answer, with potentially dangerous consequences[3]. This is currently recognised by exemptions in the Data Protection Act (1998) and from the common law of confidentiality. The UK worked hard to ensure a workable alternative to consent in the GDPR.

16. We welcome ICO's draft guidance on consent, in which they interpreted Recital 33 to allow for broad consent for research purposes. This may enable consent to be used as a legal basis more often. However, where researchers do not have consent to process special categories of data, they will need to satisfy the requirements of Article 9(2)(j) – processing of special categories of data for research purposes. The requirements for Article 9(2)(j) include "suitable and specific measures" to safeguard the fundamental rights and interests of the data subject, which should be consistent with the safeguards implemented under Article 89(1).

17. DCMS must work with the Health Research Authority and the devolved administrations to ensure there is a clear public interest legal basis available for research. Options may include, but are not limited to, the following:

    a) Establish whether legislation equivalent to the Data Protection (Processing of Sensitive Personal Data) Order 2000 would be sufficient to allow processing of sensitive data for research purposes under Article 9(2)(j). Paragraph 9 allows processing for research purposes where it is in the "substantial public interest"; is not done to support decision making about the data subject; and does not cause substantial distress or damage to the data subject or other person. The Order covers all the devolved administrations, but would need to be incorporated into new legislation.

    b) Establish the circumstances in which the Control of Patient Information regulations are sufficient to allow processing of sensitive data for research purposes under Article 9(2)(j) in England and Wales, with equivalent assessments made for the Public Benefits and Privacy Panels and Health and Social Care (control of Data Processing) Act (Northern Ireland) 2016 for Scotland and Northern Ireland respectively. This approach would result in increased workloads for the Confidentiality Advisory Group and the respective committees of the devolved administrations. DCMS must ensure they are able to meet increased demand. If this solution is adopted it is critical that this fragmented approach works across all the

[3] Joint statement – Impact of the draft European Data Protection Regulation and proposed amendments from the rapporteur of the LIBE committee on scientific research https://wellcome.ac.uk/sites/default/files/wtvm054713.pdf

devolved administrations, and does not become a barrier to sharing data between them.

c) Establish whether meeting the common law of confidentiality could be relied on as a legal basis for processing, according to Recital 41. This could be supported by ICO providing UK-wide sector specific guidance on the operation of the common law and the circumstances when it could be relied upon.

18. Article 9(2)(h) and (i) are also available to permit the processing of special categories of data for the management of health and social care and public health, including quality and safety of medicines and devices. It is important that these derogations are implemented in the UK to ensure that processing that falls on the boundary between research and healthcare, such as audit, are permitted.

19. We do not support the implementation of further conditions for the processing of genetic data, biometric data or data concerning health under Article 9(4). Other provisions of the GDPR provide an appropriate balance of derogations and safeguards.

Theme 11 – Freedom of expression and the media

20. Academic freedom of expression (Article 85) is vital for research. It is important that DCMS properly addresses the derogations provided in Article 85(2) in order to support research, particularly in the arts and humanities. However, academic freedom is outside the scope of this response.

Theme 12 – Processing of data

Recommendations:

DCMS must ensure there is a clear alternative to consent as a legal basis for processing of personal data for scientific research under Article 6, including for research activities of organisations classed as Public Authorities. DCMS should work with the HRA, the Department of Health and the devolved administrations to identify a solution. Options may include, but are not limited to, providing a dedicated public interest legal basis; relying on the Control of Patient Information regulations for health data; or relying on meeting the common law of confidentiality.

DCMS should clarify the definition of public authority, which is important to understand which legal bases are available to universities and independent research institutes with public funding.

21. Currently, under the Data Protection Act most research uses legitimate interest as the legal basis for lawfully processing data. Researchers working at organisations classed as public authorities will no longer have legitimate interest available as a legal basis. As noted above, ICO's draft guidance on consent suggests it may be possible to rely on consent as a legal basis more often. However, where researchers at public authorities cannot meet the requirements for consent to form the legal basis for processing they will almost certainly have to rely on public interest (Article 6(1)(e)). DCMS must work with the HRA and devolved administrations to ensure there is a clear public interest legal basis available for research.

22. Options may include, but are not limited to, the following:

a) Provide a dedicated public interest legal basis for scientific research for both public and private organisations in line with Recital 45 and subject to appropriate

safeguards required by Article 89(1). This would provide a clear and consistent basis for processing for research in the public interest, independent of the type of organisation carrying out the research, whether public or private sector.

b) Establish the circumstances in which the Control of Patient Information regulations would be sufficient to allow processing of data for research purposes under Article 6(1)(e) in England and Wales, with equivalent assessments made for the Public Benefits and Privacy Panels and the Health and Social Care (control of Data Processing) Act (Northern Ireland) 2016 for Scotland and Northern Ireland respectively. This approach would increase the workloads of the Confidentiality Advisory Group and the respective committees of the devolved administrations. DCMS must ensure they are able to meet increased demand. If this solution is adopted it is critical that this fragmented approach works across all the devolved administrations and does not become a barrier to sharing data between them. It is important to note this approach would result in different organisations using different legal bases for the same type of processing.

c) Establish whether meeting the common law of confidentiality could be relied on as a legal basis for processing, according to Recital 41. This could be supported by ICO providing UK-wide sector specific guidance on the operation of the common law and the circumstances when it could be relied upon.

23. We also ask DCMS to clarify the definition of public authority and how it relates to universities and independent research institutes with public funding. Under Freedom of Information law universities are considered public authorities. If this definition is applied, universities would not be able to use legitimate interest to process data and ICO have indicated that consent may not be an appropriate legal basis[4]. DCMS may choose to exclude universities from the definition of public authority for the purposes of research, which would enable them to rely on legitimate interests, like private organisations (Article 6(1)(f)). However, in the absence of another legal basis such as consent, other public authorities processing data for research, such as NHS organisations, would still need to rely on public interest as a legal basis.

Theme 13 – Restrictions

Recommendations:

DCMS should provide derogations for Articles 15 and 16, as provided for by Article 89(2). DCMS should also consider the possibility of providing a derogation for Article 13 where appropriate safeguards are met.

DCMS should work with the HRA, Department of Health and ICO to provide clarity on derogations provided in Articles 5, 14, 17, 20 and 21 in sector-specific guidance for research.

Article 5

24. The Regulation prevents personal data collected for one purpose being used for another incompatible purpose. Further processing for research is considered not incompatible

[4] Health research organisations' response to Information Commissioner's Office consultation on GDPR Consent Guidance: https://wellcome.ac.uk/sites/default/files/general-data-protection-regulation-consent-guidance-wellcome-mar17.pdf

with the initial processing purpose (Article 5(1)(b)) and can use the same legal basis (Recital 50) as the initial purpose. In addition, Article 5(1)(e) allows personal data to be stored for longer periods than necessary where it will be used for research purposes. In order to benefit from Article 5(1)(b) and (e) the safeguards set out in Article 89(1) must be fulfilled (see our response to Theme 5 – Article 89).

Article 89(2)

25. Article 89(2) allows Member State law to create derogations from Article 15 (Right of Access), Article 16 (Right to Rectification), Article 18 (Right to Restriction of Processing) and Article 21 (Right to Object).

26. The Right of Access by the data subject (Article 15) is similar to the corresponding Subject Access Request in the Data Protection Act (Sections 7 and 8). We ask that DCMS provide a derogation for Article 15 allowed for by Article 89(2), to mirror the exemption in Section 33 of the Data Protection Act.

27. The Right of Rectification (Article 16) presents specific challenges for researchers where it could undermine the integrity of data sets. We ask that DCMS provide a derogation for Article 16 commensurate with the derogation for Article 15.

28. The right to restriction of processing (Article 18) is relatively limited. The circumstances under which a data subject may request the restriction of processing do not relate to research. We do not think it is necessary for DCMS to provide the additional derogation for research available through Article 89.

29. Article 89(2) does not specifically enable Member States to provide a derogation from the Right of the Data Subject to information, when data has been collected from them (Article 13). However, we are concerned there may be cases where it is not possible to fulfil this right. We therefore ask DCMS to consider whether the GDPR provides a means to include a national derogation for scientific research where it is impracticable or impossible to provide the information required, and subject to the safeguards in Article 89(1).

Articles 14, 17, 20 and 21

30. Derogations for research for Articles 14, 17, 20 and 21 are included within the respective articles. In addition to providing the safeguards discussed under Theme 5, it is important researchers understand and are clear about their obligations and DCMS should work with the HRA, Department of Health, ICO and the devolved administrations to produce sector specific guidance, which includes clarification of the following points:

    a) Research is a purpose covered by the derogation in Article 14(5)(b) where provision of information to a data subject would prove impossible or involve a disproportionate effort.

    b) What “appropriate measures” would suffice to protect data subjects’ rights and freedoms and legitimate interests to enable the exemption to apply in Article 14(5)(b).

    c) A clear test for “impairment of the objective of the processing” to meet the exemptions in Articles 14(5)(b) and 17(3)(d).

    d) A clear definition of Public Interest to meet the exemptions from Data Portability rights (Article 20) – see our response to Themes 7 and 11.

List of organisations

Academy of Medical Sciences
Administrative Data Research Centre Wales
Administrative Data Research Network
Arthritis Research UK
Association of Medical Research Charities
Association of the British Pharmaceutical Industry
CLOSER (Cohort & Longitudinal Studies Enhancement Resources)
Economic and Social Research Council
Farr@CIPHER
Genomics England
Health Research Authority
Medical Research Council
MQ
National Centre for Population Health and Well-being Research
NHS European Office
Parkinson's UK
PHG Foundation
SAIL Databank
Sense About Science
The Brain Tumour Charity
Wellcome Trust
Wellcome Trust Sanger Institute