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Data Protection Bill – Lords’ Committee Stage Day 1

Briefing for the House of Lords, led by the Wellcome Trust

Key messages

- It is welcome that the Data Protection (DP) Bill is intended to support research, but there are significant flaws in its drafting that will have a severe negative impact on research if they are not addressed.
- We support amendments tabled by Lord Patel that seek to:
 - Ensure the ‘public interests’ legal basis is open to universities and other public bodies with a research function to be able to conduct research using personal data.
 - Ensure that interventional research is not inadvertently prohibited by the safeguards designed to protect data subjects from unwarranted processing.
- Consent is vitally important for ensuring fairness and transparency in processing personal data. However, it is unlikely to be the appropriate legal basis for data processing for research.
- Patient groups strongly support the need for alternatives to consent for research purposes.
- There is a pressing need for clear guidance for the research community on the legal bases for processing personal data, consent, safeguards, transparency and data subjects’ rights.

The importance of data for health and research

1. Data protection legislation has a major impact on how personal health and related data are used in studies. It is crucially important for biomedical research relying on the processing of personal data that the DP Bill provides a supportive and consistent legal framework.
2. The Life Sciences Industrial Strategy relies heavily on the availability and use of data held within the NS to support innovation and research that will improve patient health and care.
3. The complexity of data protection law can create a risk-averse environment for researchers wishing to process personal data for research purposes. The Bill provides an opportunity to provide much more clarity for those using personal and sensitive personal data for research purposes. This will enable data controllers and users to be confident in using data when permitted to do so and not preventing potentially valuable uses for fear of breaching data protection law.
4. The GDPR does provide the requisite provisions and flexibility for the UK to create a data protection regime that is supportive of research in the public interest. The research community is broadly positive about the final text of the GDPR.

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Alternatives to consent

5. It is important that there are alternatives to consent as a legal basis for processing, because:
 - Many research studies will, by their nature, be unable to meet standards of GDPR-compliant consent.
 - Some processing of personal data of research purposes on a non-consented basis is necessary and vitally important in the public interest.
6. Consent matters for fairness and transparency and many studies using personal data will be undertaken with informed consent. However, most informed consent processes for research could not meet GDPR (Article 7) requirements as a legal basis for processing.
7. This is because data may be used for further research purposes, by different research teams who may not be known at the time of data collection. Data also needs to be held for long periods of time, for example to ensure longitudinal follow up on the possible side effects of a drug, or to allow for replication studies to be conducted.
8. For example, biobanks are a resource that could not operate if participants had to provide explicit consent for each use of their samples or data. GDPR Recital 33 recognises this.
9. Some studies using personal data are undertaken without consent, but these are subject to robust safeguards and a careful approvals process via the Health Research Authority’s Confidentiality Advisory Group (CAG), which enables the common law duty of confidentiality to be set aside for some research purposes. At present, these studies are conducted on the basis of legitimate interests, which as a legal basis will not be available to public bodies, including NHS Trusts and universities, under the GDPR and DP Bill.
10. Access to patient records also helps researchers identify suitable participants to invite to take part in studies. This is essential for evaluating new medicines, technologies and interventions for the prevention, diagnosis and treatment of disease, such as for screening.
11. The UK has a very well-established system of governance and oversight for health-related research, including CAG, a National Research Ethics Committees, and the National Data Guardian for Health and Social Care. The safeguards provided by these entities should provide assurance that the protection of personal data and upholding of data subjects’ rights are embedded in health research.
12. GDPR clearly supports alternatives to consent for research and made clear provisions for these, with safeguards. The requirement for alternatives to consent is recognised in the GDPR provisions (e.g. Recital 33, and the Article 89(1) safeguards).
13. A significant, Europe-wide campaign, “datasaveslives”, strongly made the case for this during the passage of the GDPR. The UK lobbied the Commission and Parliament for these provisions for research, which had widespread support from patient groups. Patient groups understand and support the value of medical research that cannot meet the high bar of GDPR-compliant consent.

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14. The ICO and Health Research Authority agree that for much research, consent under Article 9(2)(a) is unlikely to be the appropriate legal basis for processing special categories of personal data.

Other issues

15. Clause 162: We support the introduction of a criminal offence for knowingly or recklessly re-identifying personal data as this will support public confidence that those who misuse personal data will be held to account for their actions.
16. Please see **Annex 1** for details of amendments tabled by Lord Patel in support of ensuring processing for medical and health research can continue
17. Please see **Annex 2** for commentary on amendments tabled by other peers that have a bearing on health and medical research.

Please contact Natalie Banner at n.banner@wellcome.ac.uk or 0207 611 8235 if you would like to discuss further.

Annex 1– Amendments tabled by Lord Patel

Section	Clause	Amendment	Detail
Part 2, Ch. 2	7	<p>Clause 7 of the Bill should be amended by inserting in line four after the word "includes", the following:</p> <p><u>"without prejudice to the generality of the expression 'necessary for the performance of a task carried out in the public interest;"</u></p> <p>and by adding new sub-clauses to the clause as follows:</p> <p><u>"The Secretary of State may by regulation add to the illustrative examples of processing that is necessary for the performance of a task carried out in the public interest or in the exercise of the controller's official authority as set out in subsection (1) of this section.</u></p> <p><u>Regulations under this section are subject to the affirmative resolution procedure."</u></p> <p>(Secondary legislation will be essential at a later date to provide the clarity needed that the legal basis for research in the public interest)</p>	<p>Purpose of amendment: To ensure that university researchers and public bodies with a research function are able to use the 'public interests' legal basis for processing personal data, and that this is can be made clear to them.</p> <p>Current drafting: Clause 7 provides a definition of lawfulness of processing personal data under GDPR Article 6(1)(e) <i>"processing of personal data that is necessary for the performance of a task carried out in the public interest or in the exercise of the controller's official authority"</i>. Clauses 7 (a)-(d) set out a narrow list of activities which would be included within the scope of "public interest".</p> <p>It is a principle of interpretation of United Kingdom statutes that where a law lists specific items, that general statements then only apply to the same kind of items. This suggests that "public interest" is a narrow concept confined to public and judicial administration.</p> <p>Problem with current drafting: The Explanatory Notes indicate that the list is not intended to be exhaustive. However, they do not indicate whether this is an appropriate legal basis for research based in universities, NHS Trusts or other public bodies.</p> <p>It is essential that public interests can be used as a legal basis for research by these organisations, as the alternatives are not suitable.</p> <p>It must be completely clear that public interest is the appropriate legal basis so that organisations that conduct research have assurance that they can use this. Data protection law can create a risk averse environment if it is not clear within the legislation what is and is not allowed.</p> <p>The regulatory Working Party for GDPR also indicated that "public interests" should be interpreted broadly, so a narrow definition may be incompatible with the intention of GDPR: <i>"'public interest' and 'official authority' grounds ... would need to be interpreted in a way as to allow public authorities some degree of flexibility, at least to</i></p>

		<p><i>ensure their proper management and functioning, just the way Regulation 45/2001 is interpreted now”.</i>¹</p> <p>Rationale for amendment: The first section of the suggested amendment allows the principle of narrow interpretation to be disapplied in this instance. This would:</p> <ul style="list-style-type: none"> • Enable types of ‘public interest’ beyond those covered by sub-clauses (a)-(d) to be considered as compatible with the intention of the clause. • Make the clause consistent with the intention expressed in the Explanatory Notes for the list (a)-(d) not to be exhaustive. <p>The advantage of the proposed wording is that it does not add specific functions to the list itself, which would invite further additions from a range of sectors and create a long list that would risk appearing exhaustive.</p> <p>The second part of the proposed amendment permits further illustration of what should be included under the ‘public interests’ legal basis at a later date, through secondary legislation. This allows further specification to be deferred if needed, but opens up the possibility of providing greater clarity for universities and other public bodies in future.</p> <p>Precedent: The use of secondary legislation to provide further provisions on a specific area of data protection law has precedent, through the Data Protection (Processing of Sensitive Personal Data) Order 2000. This amends the DPA (1998) to specify lawful bases for the processing of sensitive personal data, through the provision set out in Schedule 3 paragraph 10 of the DPA.</p> <p>Minimum Requirement from Government:</p> <ol style="list-style-type: none"> 1. There needs to be an explicit statement from Government, recorded in Hansard, and preferably stated in the Explanatory Notes, that public bodies performing research functions, such as universities, should use the ‘public interests’ legal basis for their research functions involving personal data. 2. The ICO should be required to publish a code of practice providing clear guidance on what tasks can be carried out on the public interests legal basis.
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¹ Article 29 Working Party on the draft GDPR text in 2014: http://ec.europa.eu/justice/data-protection/article-29/documentation/opinion-recommendation/files/2014/wp217_en.pdf at p. 23

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<p>Part 2, Ch. 2</p>	<p>18(2)</p>	<p>Clause 18(2) of the Bill should be amended by inserting after clause 18(2)(b):</p> <p><u>“unless the processing is carried out for research which has been approved by a relevant ethics review body”</u>;</p>	<p>Current drafting:</p> <p>In the Bill, clause 18 is explicitly linked to the legal basis for processing sensitive personal data. As “medical purposes” will no longer include medical research (as it does in Schedule 3 of DPA 1998), all processing of sensitive personal data for research purposes will need to use this legal basis.</p> <p>The policy intent of clause 18 appears to be to replicate the safeguarding function of s.33 of the DPA, ensuring that exemptions from data subject rights don’t apply if decisions are being made with respect to individuals.</p> <p>For many research purposes, this is unproblematic as the data processing does not have any bearing or impact on the data subjects themselves.</p> <p>Problem with current drafting:</p> <p>Because clause 18 now <i>also</i> serves to legitimise processing of special categories, it may create an inadvertent legal barrier for some valuable research purposes.</p> <p>It is currently ambiguous whether the wording of clause 18 would exclude interventional research, such as clinical trials, as this inherently involves processing to make “decisions with respect to a particular data subject”. Assessing eligibility, allocating participants to a trial arm and modifying the intervention, for example if evidence of adverse effects arises, all require data to be processed to enable decisions to be made with respect to particular data subjects.</p> <p>Rationale for amendment:</p> <p>Under current governance requirements, all research involving decisions being made with respect to particular data subjects would require research ethics committee approval and would always be done with the consent of the data subjects concerned.</p> <p>Consent is unlikely to meet the GDPR standard required to use consent as a legal basis for processing, but nonetheless data subjects would be aware of the processing and will have consented to participate in the research. Therefore a reasonable solution would be to specify that research ethics committee approval is needed, as an alternative safeguard to the provisions of clause 18.</p> <p>Precedent:</p> <p>A legal precedent for requiring ethics committee approval has been set in the Psychoactive Substances Act 2016, Schedule 2 clause 4, which exempts “approved</p>
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		<p>scientific research” from the prohibitions on the use of psychoactive substances set out in the Act, and defines a “relevant ethics review body”.</p> <p>Minimum requirement from Government: An explicit statement in the Explanatory Notes that “measures or decisions” excludes any measures or decisions taken with respect to a particular data subject as part of a research protocol that has been approved by a relevant ethics committee.</p>
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Annex 2 - Commentary on other amendments

Part	Clause	Amendment tabled by	Amendment text	Support/Dissent/Comment
Part 2, Chapter 2	7	Lord Clement-Jones	Page 5, line 6, leave out “includes” and insert “means”	Dissent. This amendment seeks to restrict and narrow the activities that could provide a legal basis for processing on the basis of ‘public interests’. This amendment would leave universities and other public bodies with a research function, such as NHS Trusts, with <u>no legal basis</u> for processing personal data where GDPR-compliant consent is not feasible. The amendment goes against the intentions of the Article 29 Working party on GDPR who recognised that by removing the ability of public bodies to use ‘legitimate interests’, the ‘public interests’ basis would need to be interpreted to allow flexibility.
Part 1	2	Lord Stevenson of Balmacara	Insert the following new clause: Right to protection of personal data	Dissent. While it is vitally important that data subjects have rights over the use of their personal data, there are legitimate research circumstances in which these rights cannot be upheld but where safeguards are in place. Including a clause that stipulates data subjects have rights of access to data about them would potentially create an unmanageable burden for research and contradicts the provisions of Article 89(2) in the GDPR.
Schedule 1 Part 1	3(a)	Lord Stevenson of Balmacara	Page 113, line 5, leave out paragraph (a)	Dissent. Public health provisions enable important functions such as disease registries to be created, including cancer registries. It is vitally important that these cover the whole population so that factors affecting incidence and prevalence of cancer can be understood, along with variations in treatment pathways and outcomes. Population-wide coverage cannot be achieved on a consent basis for such public health functions. Comment. Support the principle behind these amendments but it is unclear whether amending the wording is possible under implementation of the GDPR. Alternatively, the Explanatory Notes could provide the specifications required, i.e.: that ‘scientific’ is taken to be a broad term encompassing the social sciences and that ‘archiving’ includes physical and digital materials.
Schedule 1 Part 1	4(a)	Lord Stevenson of Balmacara	Page 113, line 13, after “scientific” insert “, social science”	
Schedule 1 Part 1	4(a)	Lord Stevenson of Balmacara	Page 113, line 13, leave out paragraph (a) and insert— “(a) is necessary for archiving or statistical purposes, scientific, social science or historical research, technological sciences, humanity studies or for new ideas,”	
Schedule 1 Part 1	4(c)	Lord Stevenson of Balmacara	Page 113, line 17, at end insert— “() In this paragraph, “archiving” includes collections of physical and digital materials.”	
Schedule 1 Part 1	4(c)	Lord Stevenson of	Page 113, line 17, at end insert— “() In this paragraph “research”	

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		Balmacara	includes all research conducted under the auspices of the UK Research and Innovation programme.”	
Part 2, Chapter 1	Clause 3 (3)(b)	Lord Stevenson of Balmacara	Page 3, line 31, leave out “broadly equivalent” and insert “identical in all major respects”	Support. Post-Brexit, it will be vital to achieve an adequacy agreement or something very similar. A virtually identical data protection regime will help in this regard.
Part 2, Chapter 2	Clause 6(1)(c)	Baroness Royall of Blaisdon	Page 4, line 35, at end insert— “() A college, school or university is not a public authority or public body for the purposes of the GDPR.”	Comment. The rationale for this is sensible, but it would create dissonance between how ‘public bodies’ are defined under the Freedom of Information Act and the Bill. Lord Patel’s amendment on clause 7 should have a similar effect to the intention of this amendment, but without creating this disparity in law.
Part 2, Chapter 2	Clause 7(d)	Lord Clement-Jones	Page 5, line 11, at end insert— “() In Article 6(1) of the GDPR, reference to “the public interest” is to be read as a reference to the overall good of the general public.”	Comment. Unclear on the intent and purpose of this amendment but having a clear definition of public interests that research bodies can use would be valuable.
Part 5	Clause 113 (3) (b)	Baroness Neville-Rolfe	Page 62, line 6, at end insert— “() a duty to advise Parliament, the government and other institutions and bodies on the likely consequences, economic and otherwise, to— (i) industry, (ii) charities, and (iii) public authorities, of measures relating to the protection of individuals’ rights and freedoms with regard to the processing of personal data.”	Comment. Providing clarity on the burden of compliance with data protection law would be helpful for universities, research charities and other research bodies.
Part 5	After Clause 120	Lord Stevenson of Balmacara	Insert the following new Clause— “Public interest code (1) The Commissioner must prepare and publish a code of practice which contains— (a) practical guidance in relation to the processing of personal data in the public interest, <i>Etc...</i>	Comment. Similar intent to Lord Patel’s Clause 7 amendment, demanding clarity on what constitutes public interest. ICO guidance on these issues would be welcome.