

Data Protection Bill – Second Reading

Briefing for the House of Lords 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. The following points will have a severe negative impact on research if they are not addressed:
 - The Bill does not provide a clear legal basis for universities to be able to conduct research using personal data.
 - The details of the safeguards are problematic since they do not allow clinical trials and other interventional research to benefit from the special rules for research.
- Safeguards are vitally important for ensuring data subjects' interests are protected in research. Some safeguards are included in the Bill and we welcome the introduction of sanctions for deliberate re-identification. Other important safeguards exist outside the Bill.
- 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 Data Protection (DP) Bill repeals the Data Protection Act 1998, in light of the EU General Data Protection Regulation (GDPR) which will come into effect on 25th May 2018. The GDPR permits Member States to introduce domestic legislation in certain areas, including on conditions permitting use of “special categories” of data for research purposes.

Data protection legislation has a major impact on how personal health 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. This high-level briefing focuses on the implications for biomedical research of the Bill.

Background

1. There were serious concerns about the likely impact of the GDPR on research as it was being drafted, but these were successfully resolved. The research community is broadly positive about the final text of the GDPR.
2. There is a complex framework for data protection as some safeguards and provisions exist in common law. The DP Bill does not resolve any of this existing complexity as it is focused solely on providing permitted derogations and bringing GDPR into domestic law.
3. It will be important to consider the need to retain cross-border transfers of data for research post-Brexit. The Government has recognised the value of retaining a data protection regime consistent with the EU, but clarity over whether it will seek a status of ‘adequacy’ as a third country or an equivalent arrangement, would be extremely welcome for the research community. The DP Bill does not give rise to any immediate concerns that the UK will deviate from GDPR compliance for purposes relevant to research.

SPECIFIC POINTS

Essential issues to address to avoid negative impact on research

4. It is positive that Government has included special provisions to support research as permitted by the GDPR. Government was clear in its Statement of Intent¹ that they wished to support scientists to process data safely. However, there are significant flaws in the drafting of the Bill that need to be rectified.
5. All data processing must have a legal basis. However, **the Bill does not provide a clear legal basis for universities to be able to conduct research using personal data.** There are three options, but as drafted none of these are sufficient:
 - a. *Consent*: Sometimes it is not possible to seek to consent for the use of personal data in research. In these cases research is currently permitted subject to strict safeguards. Further, it would be difficult for researchers to comply fully with stricter GDPR requirements for consent, particularly where the details of future research are not yet known. It is therefore essential that there is an alternative to consent, subject to safeguards. See [Annex 1](#) for examples of why these alternatives are needed.
 - b. *Legitimate interests*: Universities are considered 'public authorities' as defined in the Bill (Clause 6) and GDPR rules out public authorities relying on this power as a legal basis for processing.
 - c. *Public interests*: Clause 7 of the Bill appears to restricts 'public interests' to a narrow concept concerned with public and judicial administration, which would not cover university-based research.

We have received assurances from DDCMS that public interests is intended to be interpreted more broadly than the list at Clause 7 indicates. However, without a clear, explicit legal basis universities will be cautious in interpreting this clause.

Given the importance of university research and the urgent need to promote better uses of data for research, as highlighted in the Life Sciences Industrial Strategy, it is critical this oversight is rectified. An interpretation of 'public interests' that explicitly includes research purposes would be the most feasible way to address this.

6. The Bill sets out safeguards to enable research to benefit from special rules provided in the GDPR and elsewhere in the Bill, for example to allow the use of sensitive data in research (Schedule 1, Part 1) and various exemptions. This is important, but as drafted the details of the safeguards (Clause 18) are problematic. In particular, the safeguards do not allow interventional research – such as clinical trials – to benefit from the special rules, since in these cases the processing of data does involve taking measures or decisions with respect to an individual. See [Annex 2](#) for examples of why clause 18 would be problematic for interventional research.

Safeguards for data subjects

7. Safeguards are essential to ensure data is used for research in a way that is fair, safe and secure. The Bill includes some safeguards, though as noted above the detail of these is problematic for research. The UK also has a strong existing system of further

¹ https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/635900/2017-08-07_DP_Bill_-_Statement_of_Intent.pdf

safeguards for biomedical research, including ethics committees, NHS Digital's IGARD² and the Health Research Authority's Confidentiality Advisory Group.

8. In addition, it is positive that a new offence of deliberate re-identification (Part 6, s.162) is being introduced, as this will support accountability and public trust in how data is used.
9. A Private Members' Bill sponsored by Mr Peter Bone MP proposes to place The National Data Guardian for Health and Social Care on a statutory footing. It is due for second reading on 20 October. If this Bill does not receive Parliamentary assent, it should be incorporated into the DP Bill. This would build trustworthiness in the overarching data protection system for health data and send a clear message to the public that their rights are being safeguarded through this legislation.

Need for guidance

10. The DP Bill provides an opportunity to ensure clear, consistent guidance is developed that will enable researchers to contend with the new rules and changes to the legal bases for processing. In the longer term, comprehensive guidance should seek to cover both common law and data protection law to provide greater clarity. This will help overcome the risk-averse culture that stifles legitimate research uses of data due to the complexity of the law.

A more detailed briefing will be provided for Committee stage.

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

² Independent Group Advising on the Release of Data

ANNEX 1: Why research needs an alternative to consent as a legal basis for processing personal data

The use of personal data concerning health without specific, explicit consent is sometimes essential for research for the health of populations.

If researchers cannot process medical records for research without specific, explicit patient consent, they:

- **could not run cancer registries that record all cases of cancer** to help assess the levels of cancer risk in the whole population and in particular areas;
- **could not monitor the hazards of medical procedures**, such as ordering a routine CT scan which has recently been shown through record linkage to increase the risk of developing cancer many years later;
- **could not assess unexpected side-effects of routinely prescribed medicines**, for example appropriate record linkage has shown that oral contraceptives increase cervix cancer but to decrease endometrial and ovarian cancer to such an extent that oral contraceptives decrease the overall risk of getting cancer and of dying of cancer;
- **could not identify sufficiently large numbers of people with a particular disease to invite them into trials of the treatment of that disease**, for example recruitment of 20,000 suitable people into the Heart Protection Study on statins that has helped transform medical practice throughout the world, which began with identification of 400,000 patients with a hospital record of arterial disease.

ANNEX 2: Why clause 18 is problematic for interventional research

Clinical trials and other interventional research will be undertaken with the consent of patients, which is ethically essential. However, the *standard* of consent may not be GDPR-compliant as it is not always possible to specify how the data might be used beyond the purposes of the trial itself. Consent is therefore not the appropriate legal basis for much interventional research.

This means that the safeguards built into the DP Bill for processing for research purposes will apply.

Clause 18 should not apply to interventional research. This research requires the processing of personal data to make decisions about the data subject, as this is part of the necessary research design and oversight. If researchers cannot process data in this way, they will not be able to:

- Process information about a patient's condition to assess whether or not they are eligible for participating in a clinical trial.
- Process information about a patient's condition to determine what arm of a trial they should be allocated to.
- Act to remove individuals from a clinical trial if evidence arises of potential adverse effects during the course of the trial.