Freedom of Information Act 2000 (FOIA)

Decision notice

Date: **10 July 2018**

Public Authority: **The University of Bristol**
Address: **Senate House**
Tyndall Avenue
Bristol
BS8 1TH

Decision (including any steps ordered)

1. The complainant requested information about patient level data on medical care. The University of Bristol (the University) withheld the information, citing the exemption under section 40(2) of the FOIA (third party personal data) as its basis for doing so. The Commissioner's decision is that the University has correctly applied this exemption and does not require the University to take any steps.

Request and response

2. On 26 September 2017 the complainant made the following request for information:

'These requests concern 'Comparing specialist medical care with specialist medical care plus the Lightning Process for chronic fatigue syndrome or myalgic encephalomyelitis (CFS/ME): a randomised controlled trial (SMILE Trial)'. I have previously requested the trial data, your reference: FOI17 193.

In each instance following, the request is for anonymized data with personal identifiers removed.

Please provide the following patient-level data at baseline, 3 months, 6 months and 1 year assessments, where available.

1. SF-36 physical functioning scores.
2. School attendance in the previous week, collected as a percentage (10, 20, 40, 60, 80 and 100 %).
3. Chalder Fatigue Scale scores.

4. Pain visual analogue scale scores.
5. HADS scores.
6. SCAS scores.
7. Work Productivity and Activity Impairment Questionnaire: General Health.
8. Health Resource Use Questionnaire.

I am happy to receive this information in electronic format.'

3. On 3 November 2017 the University responded that it held the information but cited section 40 (personal information) of the FOIA:

'Although the research data for this study has been anonymised, it is derived from sensitive source material – information about the physical and mental health of children. Neither the research participants, nor the parents of those who were too young to give valid consent at the time, have consented to the release of this detailed, individual-level patient data into the public domain.

However, as explained in response to your previous request, the University is making the study data available to the research community on application, with appropriate safeguards in place. The Information Commissioner's Office Code of Practice on Anonymisation confirms that limited access is particularly appropriate for the handling of anonymised data derived from sensitive source material, as it maintains control over the further disclosure or use of the data and reduces the risk of exposing the data to attempts to re-identify the information. Re-identification of this sensitive personal information would expose the research participants to serious damage or distress. The University treats its responsibility to protect their personal information with the utmost seriousness.

The University considers that the limited access arrangements that have been made allow genuine researchers the ability to use this data resource for further research and statistical analysis in the public interest while protecting the privacy of the research participants, and that its release into the public domain would not be appropriate and would be in breach of the data protection principles.'

4. On 7 November 2017 the complainant requested an internal review. He argued:

'In doing so, I would ask that the University consider the following:

1. For the s.40 exemption to apply, an individual must be identifiable. The request is for anonymized data with personal identifiers removed.

2. As previously stated in communications on this question and in Matthees, health bodies and professional guidance confirm that anonymized data can be shared.

3. Anonymized data do not hold the same character of confidentiality as personalized information. Disclosure of anonymized data is permitted in law.

4. Where identity is protected, it is not a breach of confidence to disclose data to a third party without the patient's consent.

5. Matthees made clear: Where data have been anonymized, there is no legal or ethical consideration which prevents release.

6 . And: Patient consent is not necessary for the sharing of anonymized data.

7. There is no provision in the Act and its interpretation or in ICO guidance for the consideration of the source of the data.

8. Everyone's data are sensitive. The Act and the ICO guidance do not seek to discriminate between different people's data, adult or child. Indeed, arguably, it would be invidious and contrary to Human Rights legislation for the state to attempt to treat different people's data differently or to determine whose is 'more sensitive' than another's.

9. From Matthees: the test as to whether data can be released is whether they are anonymized; and anonymized data should be released. The University of Bristol acknowledge the data are anonymized.'

5. On 5 December 2017 the University provided the outcome of the internal review. It upheld its position and explained that it '*must be certain that the release of the requested information could not lead to the re-identification of the research participants.*'

Scope of the case

6. The complainant contacted the Commissioner on 16 December 2017 to complain about the way his request for information had been handled.

7. The focus of the Commissioner's investigation is to determine whether the University is entitled to rely on section 40(2) of the FOIA as a basis for refusing to disclose the withheld information.

Reasons for decision

Section 40(2) – Third party personal data

8. Section 40(2) of the FOIA states that information is exempt from disclosure if it constitutes the personal data of a third party and its disclosure under the FOIA would breach any of the data protection principles or section 10 of the Data Protection Act 1998 ('the DPA').

9. The first step for the Commissioner is to determine whether the withheld information constitutes personal data as defined by the DPA. If it is not personal data then section 40 cannot apply.

10. Section 1 of the DPA defines personal data as follows:

> *'… data which relate to a living individual who can be identified –*
> *(a) from those data, or*
> *(b) from those data and other information which is in the possession of, or is likely to come into the possession of, the data controller, and includes any expression of opinion about the individual and any indication of the intentions of the data controller or any other person in respect of the individual*.'

11. The two main elements of personal data are that the information must 'relate' to a living person and that the person must be identifiable. Information will relate to a person if it is about them, linked to them, has some biographical significance for them, is used to inform decisions affecting them or has them as its main focus.

12. Secondly, and only if the Commissioner is satisfied that the requested information is personal data, she must establish whether disclosure of that data would breach any of the data protection principles under the DPA.

Is the withheld information personal data?

13. The first consideration is whether the withheld information is personal data. The information requested is the SMILE trial data to compare specialist medical care for chronic fatigue syndrome or myalgic encephalomyelitis (CFS/ME).

14. The complainant states that he specifically asked for anonymized data with personal identifiers removed. He referred to the First-tier tribunal's decision to disclose similar trial data in EA/2015/0269, Queen Mary University of London, Alem Matthees. The Matthees case concerned the long running national clinical trial ('PACE') of 640 participants where one row of data equalled one individual trial participant and the tribunal

decision was that identification is not reasonably likely as there are no fixed or direct identifiers. Therefore, it was not personal data and section 40 did not apply.

15. The University states that there is a key distinction between the Matthees case and the current request. The Matthees case relates to a large national database of adults, whereas the SMILE study covered 100 school children, aged 12-18 in a very limited geographical area (Bristol).

16. The University was concerned that the request asked for data comprising of a high level of detail at the individual level, with no aggregation or further anonymization applied. With the limited and concise cohort of participants, there is an enhanced risk of re-identification if, for example, school records, particularly attendance records or other similar information, were obtained.

Commissioner's assessment

17. Having viewed the provided withheld information, the Commissioner is satisfied that there are no direct identifiers on the spreadsheet. However, the Commissioner understands that each line of data refers to one individual trial participant and that it contains medical scoring information and school attendance information that relates to them.

18. The Commissioner accepts that there is a key difference between this request and the Matthees case in that the scope of the research in this case was limited by numbers (100), age (12-18) and geographical area (Bristol).

19. The Commissioner's guidance on what is personal data[1] states that if information 'relates to' an 'identifiable individual' it is 'personal data' regulated by the DPA.

20. The information in this case doesn't directly identify individuals. However, because the name of an individual is not known, it does not mean that an individual cannot be identified. The aforementioned guidance states the following:

[1] https://ico.org.uk/media/for-organisations/documents/1554/determining-what-is-personal-data.pdf & https://ico.org.uk/media/for-organisations/documents/1549/determining_what_is_personal_data_quick_reference_guide.pdf

'A question faced by many organisations, particularly those responding to Freedom of Information requests, is whether, in disclosing information that does not directly identify individuals, they are nevertheless disclosing personal data if there is a reasonable chance that those who may receive the data will be able to identify particular individuals.'

21. The guidance also states:

'*The starting point might be to look at what means are available to identify an individual and the extent to which such means are readily available. For example, if searching a public register or reverse directory would enable the individual to be identified from an address or telephone number, and this resource is likely to be used for this purpose, the address or telephone number data should be considered to be capable of identifying an individual.*

When considering identifiability it should be assumed that you are not looking just at the means reasonably likely to be used by the ordinary man in the street, but also the means that are likely to be used by a determined person with a particular reason to want to identify individuals. Examples would include investigative journalists, estranged partners, stalkers, or industrial spies.'

22. A test used by both the Commissioner and the First–tier tribunal in cases such as this is to assess whether a 'motivated intruder' would be able to recognise an individual if he or she was intent on doing so. The 'motivated intruder' is described as a person who will take all reasonable steps to identify the individual or individuals but begins without any prior knowledge. In essence, the test highlights the potential risks of re-identification of an individual from information which, on the face of it, appears truly anonymised.

23. The ICO's Code of Practice on Anonymisation (https://ico.org.uk/media/fororganisations/documents/1061/anonymisation-code.pdf) notes that:

"The High Court in [R (on the application of the Department of Health) v Information Commissioner [201] EWHC 1430 (Admin)] stated that the risk of identification must be greater than remote and reasonably likely for information to be classed as personal data under the DPA".

24. In summary, the motivated intruder test is that if the risk of identification is "*reasonably likely"* the information should be regarded as personal data.

25. The main issue for the Commissioner to consider is whether or not the disclosure of the trial data along with any other information such as

school attendance records, would reveal the identities of any of the related individuals.

26. In borderline cases it can be impossible to assess re-identification risk with absolute certainty. The risk of re-identification through data linkage is essentially unpredictable because it can never be assessed with certainty what data is already available or what data may be released in the future.

27. However, having had the opportunity to review the detailed fatigue and anxiety score details and the school attendances in the withheld information, the Commissioner considers that it is more than remote and reasonably likely that individual children could be identified by combining this information which 'relates to' individuals receiving specialist medical care for chronic fatigue syndrome or myalgic encephalomyelitis (CFS/ME) with information from other sources, such as school attendance records.

28. Therefore, the Commissioner is satisfied that the requested information in this case constitutes personal data.

Would the disclosure be fair?

29. The Commissioner has gone on to establish whether disclosure of that data would breach any of the data protection principles under the DPA.

30. The first principle requires, amongst other things, that personal data is processed fairly and lawfully. The Commissioner has first considered whether the disclosure of the withheld information would be fair.

31. In considering whether disclosure of this information would be fair the Commissioner has taken the following factors into account:

    - whether disclosure would cause unnecessary or unjustified damage or distress to the individuals concerned;

    - the individuals' reasonable expectations of what would happen to their information; and

    - are the legitimate interests of the public sufficient to justify any negative impact to the rights and freedoms of the individuals concerned.

32. The University explained that '*there is no consent to circulate or publish it in this way, and release and the potential for re-identification could expose the participants to serious damage or distress'*.

Sensitive personal data

33. Any consideration of fairness must first determine whether the requested information is defined as sensitive under the DPA. Section 2 of the DPA defines sensitive personal data as information which relates to:

    (a) racial or ethnic origin
    (b) political opinions
    (c) religious beliefs
    (d) trade union membership
    (e) physical or mental health
    (f) sexual life
    (g) criminal offences, sentences, proceedings or allegations.

34. The Commissioner notes that the information in this case falls under section 2(e) of the DPA as it relates to the physical and mental health of the children who participated in the study. The mere fact that this is medical evaluation data collected and produced during the course of a clinical trial does not alter its nature as sensitive medical treatment relating to each participating patient.

35. The nature of the illness was considered in detail in a previous decision notice https://ico.org.uk/media/action-weve-taken/decision-notices/2014/947420/fs_50514995.pdf:

    'this medical data relates to a mentally and physically debilitating condition of unknown cause, suffered by a small minority of the population and which has presently limited interventions. CFS/ME is often long-term with serious financial, professional and personal consequences. There is no reason to doubt that most people of normal sensibilities would wish to keep information relating in any way to their illness private under these circumstances and would realistically be greatly distressed if they were to be identified.'

36. By its very nature, medical treatment and data has been deemed to be information that individuals regard as the most private information about themselves. Further, as disclosure of this type of information is likely 'to have a detrimental or distressing effect' on the data subject, the Commissioner considers that it would be unfair to disclose the requested information and therefore be in breach of the DPA.

37. The Commissioner also notes that the University has put an appropriate process in place governing limited access to research data of this nature. This incorporates safeguards to ensure that only bona fide researchers have access to controlled information, that they intend to use it appropriately and that they undertake to protect it by signing a Data Access Agreement. All requests are assessed by a Data Access

Committee. Therefore the Commissioner considers that this limited access satisfies the legitimate interests of the public under FOIA.

Conclusions

38. Balancing the above, the Commissioner is satisfied that disclosing the patient level data from the medical care trial in Bristol is personal data and that the individuals would have no reasonable expectation that the information in question would be disclosed to the world at large.

39. Therefore, the Commissioner upholds the University's application of the exemption provided at section 40(2) of the FOIA.

Right of appeal

40. Either party has the right to appeal against this decision notice to the First-tier Tribunal (Information Rights). Information about the appeals process may be obtained from:

    First-tier Tribunal (Information Rights)
    GRC & GRP Tribunals,
    PO Box 9300,
    LEICESTER,
    LE1 8DJ

    Tel: 0300 1234504
    Fax: 0870 739 5836
    Email: GRC@hmcts.gsi.gov.uk
    Website: www.justice.gov.uk/tribunals/general-regulatory-chamber

41. If you wish to appeal against a decision notice, you can obtain information on how to appeal along with the relevant forms from the Information Tribunal website.

42. Any Notice of Appeal should be served on the Tribunal within 28 (calendar) days of the date on which this decision notice is sent.

Signed .....

Pamela Clements
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