

## Freedom of Information Act 2000 (FOIA)

### Decision notice

**Date:** 23 January 2014

**Public Authority:** Queen Mary University London  
**Address:** 327 Mile End Road  
London Borough of Tower Hamlets  
E1 4NS

#### Decision (including any steps ordered)

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1. The complainant has requested information relating to the PACE Trial carried out by Queen Mary University London (QMUL).
2. The Commissioner's decision is that QMUL has correctly applied section 40(2) to the withheld information. Therefore the Commissioner does not require the public authority to take any steps in relation to this decision notice.

#### Request and response

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3. On 19 March 2013, the complainant wrote to QMUL and requested information in the following terms:
  - a) *"Number of participants at outcome with an SF-36 Physical Function score of 85 or more (Protocol defined recovery)*
  - b) *Number of participants at outcome with an SF-36 Physical Function score of 75 or more (Protocol defined improvement)*
  - c) *Number of participants at outcome with an SF-36 Physical Function score 50% higher than their baseline score (Protocol defined improvement)*
  - d) *Number of participants at outcome with a Chalder Fatigue Scale score of 3 or less in Bimodal Mode or 11 or less in Likert Mode (Protocol defined improvement/recovery)*

- e) *Number of participants at outcome with a Chalder Fatigue Scale score 50% lower than their baseline score (Likert Mode please if possible)*
- f) *Number of participants at outcome who met both conditions in 1 and 4*
- g) *(and if you can possibly manage this:) Number of participants at outcome who met either 2 OR 3 AND either 4 OR 5. (Protocol defined overall improvers)*

*I do not know how difficult it would be for you to access the database, but my main interest is in 1, 4 and 6 and I would really appreciate these figures at your earliest convenience.*

*Further to my earlier message, I should have added that if possible, I would be grateful for the data for each trial arm, CBT, GET, SMC and APT."*

- 4. QMUL responded on 15 April 2013 and stated that the information was not held.
- 5. The complainant wrote to QMUL again stating:

*"In the interests of clarity and so that I may proceed:*

*Does QMUL hold or have access to the data that can be used to derive the information that I requested or know who does hold the data? The PACE Trial Protocol (for which I have requested correlating information) gives Queen Mary University London as the address for "the PACE Trial Group".*

*I note that in response to a previous FIO request you provided data about PACE Trial participant baseline measures (Queen Mary, University of London. FOI Request: 2013/F42). The information provided for that request showed how many participants in each trial arm met or not - 'normal range' at baseline.*

*Am I correct in deducing that your reply to my FOI request shows that QMUL hold or have access to baseline information but NOT outcome information from the trial?*

*Or alternatively, am I to understand that the college had the baseline data matching the previous FOI request regarding 'normal range' already to hand, and if so, please tell me on what date that data was generated and for what purpose; since I must assume that it was not generated in response to the FOI request?*

6. On 17 April 2013 the complainant requested an internal review. QMUL responded on 8 May 2013 and provided an explanation as to why it considered that the information was not held.
7. On 16 May 2013 the complainant made a new request in the following terms:

*"Perhaps it would be convenient if I modify the request to data requiring no analysis? This might allow us to continue our review, though if it suits your procedures please treat this as a new request if you wish:*

*a) PACE Trial Primary Outcome Measure scores for the Short-Form 36 (SF-36) all participants*

*b) PACE Trial Primary Outcome Measure scores for the Chalder Fatigue Scale (CFQ) all participants.*

*The order is unimportant though each set should be similarly ordered. Please mention the order correlation -- i.e. by recruitment date, random participant number assignment etc."*

8. On 1 July 2013 QMUL responded and refused to provide the requested information citing section 40(2) and section 41 of the FOIA as its basis for doing so.
9. Following an internal review QMUL wrote to the complainant upholding its original position.

## **Scope of the case**

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10. The complainant contacted the Commissioner on 2 October 2013 to complain about the way his request for information had been handled.
11. The Commissioner considers the scope of this case to be to determine if QMUL correctly applied section 40(2) and section 41 to the withheld information.

## **Background**

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12. The PACE trial was a clinical trial carried out by QMUL commencing in 2002. This PACE (Pacing, graded Activity and Cognitive behaviour therapy: a randomised Evaluation) trial was a large scale trial to test

and compare the effectiveness of four of the main treatments available for people suffering from chronic fatigue syndrome (CFS), also known as myalgic encephalomyelitis (ME).

13. Thus the trial required the collection of vast amounts of medical baseline and treatment results over the period 2005-2010 from the 640 patients who participated in the Trial.
14. Results from the PACE trial have been published in The Lancet and the QMUL website (<http://www.pacetrials.org/>) provides further information and details of the trial.
15. In a previous decision notice (FS50451416) the Commissioner has noted that the PACE trial is controversial and there are some organisations and individuals opposed to the treatment methods used.

## **Reasons for decision**

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### **Section 40(2) – third party personal data**

16. Section 40(2) of FOIA provides an exemption for information which is the personal information of an individual other than the applicant, and where one of the conditions listed in section 40(3) or 40(4) is satisfied.
17. In this case the relevant condition is contained in section 40(3)(a)(i). This applies where the disclosure of information to any member of the public would contravene any of the principles of the Data Protection Act (DPA) 1998. This is an absolute exemption, and is therefore not subject to a public interest test.
18. In order to establish whether this exemption has been correctly applied the Commissioner has first considered whether the withheld information is the personal data of third parties, namely those taking part in the PACE Trial.
19. Personal data is defined in the DPA as information about a living individual who can be identified from that information, or from that information and other information in the possession of, or likely to come into the possession of, the data controller.
20. In considering whether all the data requested is personal data the Commissioner has noted the description given by QMUL. It explained that the requester has sought primary outcome measure scores from the PACE trial correlated to each individual. The information which has been requested consists of data derived from each living individual who took part in the PACE trial linked to their assigned PIN and date of

randomisation (at the least). It is raw medical data, an indicator of a person's health, similar to that which has been requested previously and the ICO has found should not be disclosed<sup>1</sup>. In the view of QMUL, all of it is (sensitive) personal data relating to the individuals in their private lives and who voluntarily took part in the trial.

21. QMUL stated that the final part of the complainant's request is critical in determining how it should respond as it specifically asks for the data at an individual level and for the two datasets to be correlated. If QMUL were to provide just the two columns consisting of the outcome scores, QMUL does not believe this is what the applicant is requesting due to the qualification specified.
22. QMUL explained that each row of the spreadsheet relates to an individual. By adding the other fields and more, such as treatment arm, it becomes information which could allow a party to identify an individual and so is sensitive personal data, being medical data that relates to a trial participant. For instance, the randomised date is personal data relating to an individual and if one knew when this date was, coupled with other information they could identify a participant and know their outcome scores. As an example, in April 2007 there were only 12 patients randomised during that month. This is a small percentage of the total number of patients who took part in the trial. It is possible the requester or someone else may be able to identify individuals once the data is in the public domain, with this medical data for said individuals disclosed and free to be published.
23. The Commissioner has also taken into account his Code of Practise on Anonymisation: managing data protection risk<sup>2</sup>. This refers to the motivated intruder risk of re-identification and the issues for an organisation to consider when making a decision on whether datasets such as in this case will lead to the identifiability of individuals. On page 25 of this Code of Practise it is acknowledged that when considering large datasets or collections of information such as in this case it will be difficult to conduct an assessment of the likelihood of individuals having and using the prior knowledge necessary to facilitate re-identification. As such it will often be acceptable to make a more general assessment of the risk of prior knowledge leading to identification, for at least some of

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<sup>1</sup> [http://www.ico.org.uk/~media/documents/decisionnotices/2013/fs\\_50484575.ashx](http://www.ico.org.uk/~media/documents/decisionnotices/2013/fs_50484575.ashx)

<sup>2</sup>

[http://www.ico.org.uk/for\\_organisations/guidance\\_index/~media/documents/library/Data\\_Protection/Practical\\_application/anonymisation\\_code.ashx](http://www.ico.org.uk/for_organisations/guidance_index/~media/documents/library/Data_Protection/Practical_application/anonymisation_code.ashx)

the individuals recorded in the information and then make a global decision about the information.

24. Given the above and the arguments provided by QMUL regarding the possibility of identification the Commissioner is satisfied that the general assessment and global approach taken by QMUL in concluding all the requested information is personal data is the correct approach to take here.
25. The Commissioner is therefore satisfied that all the information is the personal data of third parties and that some of it is sensitive personal data.

**Would the disclosure be fair?**

26. The Commissioner has gone on to consider whether the disclosure of this information would be in breach of the first principle of the DPA.
27. 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.
28. 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.
29. QMUL believes that disclosure of the information here would breach the first data protection principle in that it would not be fair or lawful to disclose it. Section 40(2) by virtue of Section 40(3)(a)(i) provides that personal information is exempt in this event.
30. As explained above, the data relates to living individuals. The mere fact that this is medical evaluation data collected and produced during the course of a randomised clinical trial does not, nor should it, in any way serve to alter its nature as sensitive medical data relating to each participant.
31. QMUL explained that although the PACE trial is a relatively large study, sufferers of CFS/ME comprise only 1% of the general population. Given

the limited pool of eligible participants and that the requester has asked for data at the individual-participant level, it is likely that these individuals could be identified should it be disclosed to the public. This is raw data and releasing it to the world at large – as any release under FOIA is – could mean that the data subjects could be identified or identifiable from it or from other data that could fairly readily come into the possession of the requester or others. This would mean disclosing sensitive personal data of participants.

32. QMUL further stated that as the CFS/ME patient community is very close, active and motivated in numerous cases to challenge the outcomes of studies with results which do not comport with their beliefs as to the causes and treatment of CFS/ME, the possibility that individuals would be sought to be identified in this regard once the data was made public cannot be considered speculative or remote. Thus, it must be concluded that this is sensitive personal data. As mentioned above, QMUL has read the qualification to the request as the applicant requiring additional fields for each row of data. The more that are supplied (the requestor having written "etc.") the more personalised the data becomes.
33. Fair processing must largely be determined with regard to the circumstances under which the data has been obtained and processed and data subjects' reasonable expectations. QMUL consider that this should entail analysis of whether the data subject has been given adequate, truthful information about the processing and the data controller, so as to make the process transparent and understandable to the data subject and thus enable him to make an informed, voluntary decision as to whether to consent to the processing. Of course, this, in turn, impacts on the validity of the consent for purposes of legitimate processing.
34. QMUL stated that by its very nature as 'sensitive', medical data under the Data Protection Act 1998 is considered to be that which would prove to be a source of considerable embarrassment, distress or humiliation if disclosed publicly. Moreover, here the data does not concern a simple clinical 'put a plaster on it' or 'cut it off/out and all done' medical treatment that everyone experiences. Rather, 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. The Information Tribunal has noted<sup>3</sup> "disclosure under FOI is an unlimited disclosure to the public as a whole without conditions". Once published to the world at large, if someone were to use it to identify individuals who are suffering from CFS/ME and participated in the trial, it could result in damage to them and/or distress. In an area of contentious research and treatment, patients or QMUL should not have to prove that patients have been or will be vilified or ridiculed in the public CFS/ME fora for participating in a research trial in order to keep their medical data which results from that participation, confidential. Few if any patients are subject to such a burden. QMUL is aware of researchers having been publicly vilified and threatened for conducting the research or reaching the relevant findings: see for example <http://jdc325.wordpress.com/2012/11/17/mecfs-harassment-of-researchers/>. Patients should be able to rely on assurances of confidentiality. To expect otherwise is itself unfair given the nature of the data here.

35. QMUL explained that CFS/ME is of yet unknown cause and with varying physical symptoms including fatigue or exhaustion that are often of necessity self-reported and which therefore have led to unjustified labels such as 'malingerer' being applied to its sufferers. The possibility that data may be released which could lead to the individuals being identified publicly as recipients/shirkers would likely cause great personal distress.
36. Not only did these patients not give explicit consent to process further this data for public disclosure, but they were also expressly advised of the specific and limited purposes for its further processing beyond it being held and used by their local PACE trial clinicians and provided with specific assurances of data confidentiality as the basis for their voluntary participation in the clinical trial.
37. The Commissioner has viewed the trial protocol and is satisfied that it sets out strict criteria in relation to how information will be stored and who will have access to it. This is what the patients have agreed to.
38. The PACE Trial patients would have no reasonable expectation that their medical information would be disclosed beyond the specified purposes

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<sup>3</sup> Guardian & Brooke v The Information Commissioner & the BBC (EA/2006/0011 and EA/2006/0013) (following Hogan and Oxford City Council v The Information Commissioner (EA/2005/0026 and EA/2005/0030))



never mind to a member of the public and the world at large. That such expectations that the sharing limitations indicated in the consent and patient information disclosures were, and are reasonable expectations, is clearly supported by the recent policy guidance of the Trial's funding body, the Medical Research Council. Indeed, the MRC's policy recommends sharing such medical research data only with "bona fide researchers" from higher education institutions which will be committed to protecting patient confidentiality.

(See, *Medical Research Council Data Sharing Policy*, available at: <http://www.mrc.ac.uk/Ourresearch/Ethicsresearchguidance/datasharing/Policy/index.htm>)

39. On balance QMUL considered that there are no public interests which serve here to alter the balance of fairness. While there are always the general transparency and cost monitoring concerns that arise with public authorities, there has been full disclosure about the PACE trial, its protocols, staffing and costs and the projected and actual publications to disclose its findings. Indeed, the PACE trial has maintained a website with publication of all such relevant data<sup>4</sup>. There continues to be ongoing research and examination of the patient data and publication.
40. QMUL further explained that in addition, the PACE trial's main findings have already been independently replicated by The Norwegian Knowledge Centre for the Health Services, a member of the Cochrane university group of medical researchers. QMUL considered this sharing, under circumstances of strict patient confidentiality, for such scientific audit of the quality of the Trial findings, important in light of the very public concerns raised about them.
41. Given the level of public transparency and now independently replicated results, QMUL considers that there is no legitimate public interest which would justify the disclosure of what clearly is sensitive personal data of patients whose voluntary consent to collect it and analyse it for scientific research was based on these specified limitations as to the purposes of the processing. The patients' expectations that this consent limitation would be honoured were then and continue now to be reasonable. To alter the rules now and expose these patients to public identification would be patently unfair. The ICO guidance states, 'where the conclusion is that the disclosure would be unfair, and so in breach of the

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<sup>4</sup> [www.pacetrial.org](http://www.pacetrial.org)

first principle, this would be the end of the matter and the information would not be disclosed'.<sup>5</sup>

42. QMUL stated that as previously noted, this trial was not mere data collection, but patient treatment and follow up over the course of several years. That the trial was also for research and publicly-funded should not lead to public disclosure without compelling reasons. Indeed, much patient data is used for research and in the UK medical treatment is typically publicly funded. Yet neither of these rationales would serve to mandate wholesale that patient data be publicly disclosed. This clearly would serve to undermine the importance of the confidential nature of the medical clinician/patient relationship.
43. The Commissioner is unable to conclude that disclosure of the withheld information is necessary to meet a legitimate public interest.
44. Based on the above, the Commissioner is satisfied that the withheld information is personal data and that disclosure would breach the first data protection principle as it would be unfair to the individuals concerned.
45. As the Commissioner has determined that it would be unfair to disclose the requested information, it has not been necessary to go on to consider whether disclosure is lawful or whether one of the conditions in Schedule 2 or 3 of the DPA is met.
46. The Commissioner therefore upholds QMUL's application of the exemption provided at section 40(2) of the FOIA. Consequently, he has not gone on to consider the application of section 41.

## Right of appeal

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47. 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: 0116 249 4253

Email: [GRC@hmcts.gsi.gov.uk](mailto:GRC@hmcts.gsi.gov.uk)

Website: [www.justice.gov.uk/tribunals/general-regulatory-chamber](http://www.justice.gov.uk/tribunals/general-regulatory-chamber)

48. 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.
49. 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**  
**Group Manager, Complaints Resolution**  
**Information Commissioner's Office**  
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**Water Lane**  
**Wilmslow**  
**Cheshire**  
**SK9 5AF**