

Freedom of Information Act 2000 (FOIA)

Decision notice

Date: 27 October 2015

Public Authority: Queen Mary University of London
Address: Mile End Road
London
E1 4NS

Decision (including any steps ordered)

1. The complainant requested information related to a clinical trial concerning treatments for chronic fatigue syndrome ("CFS") carried out by Queen Mary University of London ("the University"). The University withheld the information under the exemptions in sections 22A, 40(2), 41 and 43(2) of FOIA.
2. The Commissioner's decision is that the University has incorrectly applied sections 22A, 40(2), 41 and 43(2) of FOIA to the withheld information.
3. The Commissioner requires the public authority to take the following steps to ensure compliance with the legislation.
 - To disclose to the complainant the information to which it has applied sections 22A, 40(2), 41 and 43(2) of FOIA.
4. The public authority must take these steps within 35 calendar days of the date of this decision notice. Failure to comply may result in the Commissioner making written certification of this fact to the High Court pursuant to section 54 of the Act and may be dealt with as a contempt of court.

Request and response

5. On 24 March 2014, the complainant wrote to the University and requested information in the following terms:

"Previous FOI requests [1][2] have asked for the release of PACE Trial results according to the outcome measures laid out in the trial protocol published in 2007 but since abandoned, and for additional summary statistics on the trial participants or at least the subgroup classified as 'recovered' after the 52-week followup period. [3] These requests have been denied because the information was not held in final form and the calculations required to attain them from data that is held would supposedly exceed the limit of £450 (calculated as the estimated cost of one person spending 18 hours in determining whether the information is held, then locating, retrieving and extracting the information). [4] A few of the comments posted in response have raised doubts over whether acquiring the data and performing relatively simple calculations would really take over 18 hours to perform.

In order to help ease the burden of staff having to perform the required calculations themselves once the relevant data is located and retrieved, I would like to request the following selection of baseline and 52-week followup data on all 640 individual PACE Trial participants for which the data exists, in a spreadsheet or equivalent file with separate columns for each variable:

- SF-36 physical function scores (range 0-100 points) [baseline and 52-week followup];*
- CFQ fatigue Likert scores (range 0-33 points) [baseline and 52-week followup];*
- CFQ fatigue bimodal scores (range 0-11 points) [baseline and 52-week followup];*
- Oxford criteria CFS caseness (does participant meet criteria, yes or no) [52-week followup only];*
- Participant-rated CGI scores (range 1-7) [52-week followup only];*
- Doctor-rated CGI scores (range 1-7) [52-week followup only];*
- 6MWT walking distances (in meters) [baseline and 52-week followup];*
- The group which each participant was allocated to after randomisation (i.e. either to APT, CBT, GET, or SMC).*

If granted, please make sure that each individual row only contains values from the same participant, as is common practice for such data in spreadsheets, so that more than one variable can be analysed at a time. To clarify, I am requesting only 'anonymised' data, I am not requesting any information which can identify individual participants (not even the participant ID

numbers if those are deemed to be inappropriate to include, so long as each individual row only contains values from the same participant).

1. https://www.whatdotheyknow.com/request/pace_trial_recover_y_rates_and_po

2. https://www.whatdotheyknow.com/request/pace_trial_recover_y_rates_and_po_2

3. https://www.whatdotheyknow.com/request/6min_walking_test_data_recovered

4. http://ico.org.uk/for_organisations/freedom_of_information/guide/refusing_a_request

6. On 22 April 2014 the University responded and withheld the requested information citing the exemptions in sections 40(2) and 41 of FOIA.
7. On 18 June 2014 the complainant requested an internal review.
8. The University provided the outcome of its internal review on 16 September 2014 and maintained its original position to withhold the information requested.
9. During the course of the Commissioner's investigation, the University also applied the exemptions in sections 22A and 43(2) to the withheld information.

Scope of the case

10. The complainant contacted the Commissioner on 15 December 2014 to complain about the way his request for information had been handled.
11. The Commissioner considered whether the University had correctly applied the exemptions it had cited to the withheld information.

Background

12. The PACE (Pacing, graded Activity and Cognitive behaviour therapy: a randomised Evaluation) trial was a clinical trial carried out by the University which commenced in 2002. It 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. The trial required the collection of large amounts of medical baseline and treatment results over the period 2005-2010 from the 640 patients who participated in it.
14. Results from the PACE trial have been published in The Lancet. The University's website (<http://www.pacetrial.org/>) provides further information and details about the trial.
15. The Commissioner notes that the PACE trial has resulted in some public debate, with some organisations and individuals being opposed to the treatment methods used.

Reasons for decision

16. The University argued that the withheld information was exempt from disclosure under sections 22A, 40(2), 41 and 43(2) of FOIA. The Commissioner considered the application of each of the exemptions in turn.

Section 22A – Information derived from a programme of research

17. The University sought to rely on section 22A as a basis for withholding the requested information.
18. Section 22A provides that:

"(1) Information obtained in the course of, or derived from, a programme of research is exempt information if—

(a) the programme is continuing with a view to the publication, by a public authority or any other person, of a report of the research (whether or not including a statement of that information), and

(b) disclosure of the information under this Act before the date of publication would, or would be likely to, prejudice—

(i) the programme,

(ii) the interests of any individual participating in the programme,

(iii) the interests of the authority which holds the information, or

(iv) the interests of the authority mentioned in paragraph (a) (if it is a different authority from that which holds the information)."

19. The University explained that all of the requested information came from the PACE trial, a large-scale, randomised clinical trial investigating treatments for chronic fatigue syndrome or myalgic encephalomyelitis (CFS/ME), of which it was the main sponsor and from which it held all of the raw data. It went on to explain that the trial closed to recruitment in 2009, and follow up continued until mid-2012. However, analysis of the data continues to this day and papers continue to be published.
20. As regards the University's application of section 22A to the withheld information, the Commissioner noted that this provision came into effect on 1 October 2014. However, the complainant made his request to the University on 24 March 2014 and the University provided its response on 22 April 2014. The Commissioner informed the University that he considers the circumstances that existed at the time that a request was made in reaching any decision and queried the basis on which the University believed that section 22A could be applied retrospectively.
21. The Commissioner has set out below the University's arguments as to why it believed he should consider the application of section 22A to the request. The University argued that:

"In line with precedents such as Information Commissioner v Home Office [2011] UKUT 17 (AAC)(noting that absent the ability to rely on new exemptions, the ability to fully consider the public interest and the rights of third parties with respect to information to be disclosed would be hampered), we believe reliance on this exemption at this stage is important. QMUL acknowledges that the exemption in question was not in effect when the information was originally requested. While we further recognise that, in keeping with the Commissioner's consideration as indicated here, there normally exists a presumption against retroactive application of legislation, it has been held, however, that this presumption 'expresses no rigid or absolute rule'. Barber v Pigden [1937] 1 KB 664, 678 (CA). Rather, courts have considered whether this would be in keeping with intent of the statutory change. Ibid. They have examined whether the new law is applied to circumstances which have fully taken place and impair vested rights a party possessed, increase a party's liability for past conduct, or impose new duties with respect to transactions already completed. See Phillip v Eyre (1870-71) L.R. 6 Q.B. 1, 24-27 (holding that despite the presumption, such retrospective application cannot be pronounced naturally or

necessarily unjust and requires an examination of the circumstances which can vary from case to case); accord, Polyukhovich v Commonwealth of Australia [1991] 172 CLR 501 ('the injustice which might be inflicted by construing an enactment so as to give it a retrospective operation may vary according to its subject matter')."

22. The University went on to inform the Commissioner that:

"Circumstances where the courts have found the retroactive application of a law to be unwarranted have typically involved instances where to hold otherwise would manifestly shock a sense of justice, i.e. be inherently unfair, such as where: an act legal before the statute was made illegal, but see Polyukhovich v Commonwealth of Australia [1991] 172 CLR 501 (finding that although ex post facto application of criminal law usually creates unjust legal consequences which the presumption seeks to prevent, a subsequent war crime enactment a reasonable exception); a defence existing under the law at the time of the events and to which the bankrupt was then entitled was subsequently removed, see R v Griffiths [1891] 2 QB 145; or, a right vested in a sale of property would be voided due to a subsequent time limited registration requirement rendering compliance impossible, see Hicksen v Darlow (1883) 23 Ch D 690 (CA).

As the Polyukhovich court further noted: 'Indeed, justice may lay almost wholly upon the side of giving remedial legislation a retrospective operation where that is possible... . With legislation of that character, if the ordinary rule be couched in terms of a presumption against retrospectivity, it must, at best, be a weak presumption...' (citations omitted). Ibid at para 17.

Accordingly, it has been held that retroactive application that might seem unjust from the perspective of one person may be justified from the perspective of another. George Hudson Ltd. v. Australian Timber Workers' Union (1923) 32 CLR 413, 434. Therefore, the whole of the circumstances must be considered."

23. The University was of the view that there was no manifest injustice in this case in the ICO's retroactive application of the exemption in section 22A. It argued that:

"The holding in Southwest Center for Biological Diversity v. US Department of Agriculture, 314 F.3d 1060 (9th Cir. 2002) where the Court determined that it could apply an FOIA exemption (that agency may withhold information about the location of

endangered species) enacted after the request but before the appeal in question as it did not have an impermissible retroactive effect. In reaching this decision, the US Court of Appeals for the Ninth Circuit determined that the applicable test of impermissibility required consideration of "whether it would impair rights a party possessed when he acted, increase a party's liability for past conduct, or impose new duties with respect to transactions already complete", factors very similar to those applied by other common law systems as noted above. Ibid (quoting the US Supreme Court in Landgraf v. USI Film Products, 511 U.S. 244, 273 (1994). The 9th Circuit specifically rejected the requestor's assertion that it had a right to the information when it made its request or sought review that it would lose by virtue of the new exemption's application. The Court instead considered that the requestor had not taken a significant act in reliance on a settled expectation under the law (such as having waived a legal right in a promised exchange or undertaken a course of action in reliance on a representation) but merely requested information and sought an appeal when it was refused. It had not been prejudiced, therefore, under the Landgraf test. Moreover, the Court considered that the application of the exemption was in keeping with Congressional intent here to protect the endangered species."

The ECHR has been held, moreover, not to preclude retroactive application, foreclosing it rather where a right to a fair trial would be imperilled or property lost. See, eg, St Matthews (West) and others) v HMRC ([2014] EWHC 1848 (Admin); Huitson [2011] EWCA Civ 893 (no infringement of art 6, ECHR where legislation under challenge did not impose a liability to tax but rather removed an alleged, but not established, right to tax relief).

The circumstances here are similarly that the requestor has not been prejudiced. There is no manifest injustice. Rather, the exemption's application would be in keeping with Parliament's intent to protect the public interest in research by allowing authorities to shield information collected as part of a programme of research where that disclosure would prejudice the research programme, the authority's interests, those of participants in the research programme or other authorities. In this case, QMUL has demonstrated that prejudice would be likely to several interests: those of the patients, the research programme, the investigators and QMUL as evidenced by the above analysis. The addition of the Section 22A exemption served to remediate a lacuna in the FOIA and provide an equivalent provision to that which the Scottish Act had always had, thereby equalizing protections

across the UK's research institutions. This is important since, as here, research institutions typically collaborate in such trials."

24. The Commissioner notes the arguments presented by the University regarding the application of section 22A. However, he is aware of the general presumption in English law against statutes operating retrospectively. He further notes that in passing the amendment to the Freedom of Information Act contained in section 22A, Parliament did not expressly provide that it should have retrospective effect. In the absence of any such clear statement from Parliament, the Commissioner is of the view that section 22A is not applicable to requests that had already been made and responded to prior to it coming into force on 1 October 2014. As the University had already provided a response to the complainant's request, and had even provided the outcome of its internal review, prior to that date, the Commissioner has determined that section 22A is not applicable.

Section 40(2) – Personal information

25. The University argued that section 40(2) was applicable to the withheld information.
26. Section 40(2) provides an exemption for information which is the personal information of an individual other than the complainant and where one of the conditions listed in section 40(3) or 40(4) is satisfied.
27. Section 40(2) provides that –

"Any information to which a request for information relates is also exempt information if-

- (a) it constitutes personal data which do not fall within subsection (1), and*
- (b) either the first or the second condition below is satisfied."*

28. Section 40(3) provides that –

"The first condition is-

(a) in a case where the information falls within any of paragraphs (a) to (d) of the definition of "data" in section 1(1) of the Data Protection Act 1998, that the disclosure of the information to a member of the public otherwise than under this Act would contravene-

- (i) any of the data protection principles, or*

(ii) section 10 of that Act (right to prevent processing likely to cause damage or distress), and

(b) in any other case, that the disclosure of the information to a member of the public otherwise than under this Act would contravene any of the data protection principles if the exemptions in section 33A(1) of the Data Protection Act 1998 (which relate to manual data held by public authorities) were disregarded."

29. In this case the relevant condition is contained in section 40(3)(a)(i). This applies where the disclosure of the information to any member of the public would contravene any of the principles of the Data Protection Act 1998 ("DPA").

30. The Commissioner therefore considered:

(1) whether the withheld information constitutes personal data; and if so

(2) whether disclosure would breach one of the data protection principles.

(1) Does the withheld information constitute personal data?

31. In order to establish whether section 40(2) had been correctly applied, the Commissioner first considered whether the withheld information is the personal data of parties other than the complainant.

32. 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.

33. The University informed the Commissioner that it considered that the withheld information contained the personal data of the individuals who had volunteered to participate in the PACE trial. It was the University's view that all of the specific data which had been requested from the trial was sensitive personal data as it consisted of data derived from each living individual who took part in the PACE trial. It noted that there were a number of variables, which the complainant had specifically asked be linked by supplying the data with one row corresponding to one trial participant.

34. In the Commissioner's view the two main elements necessary for information to be personal data are that the information must 'relate' to a living person and that the person must be identifiable.
35. The University noted that the complainant had claimed that the requested data would be in an anonymised form so that individuals could not be identified. However, the University was of the view that this was not the case.

Why the University believed that the requested information was not satisfactorily anonymised

36. The University informed the Commissioner that it did not believe that the requested information was in a satisfactorily anonymised form given the number of variables, with one row for each individual. It stated that it had formed this view taking account of the motivated-intruder risk outlined in the ICO's Code of Practice on Anonymisation. The University initially explained that:

"The number of people with CFS/ME is around 1% of the population; the number of trial participants was 640. Even if the disclosure risk for third parties to be able to identify individuals were low, the possibility that an individual who took part in the trial could identify themselves is much higher, especially since much of these health data were self-rated. It is not possible therefore to render the data completely anonymous given this, the quantity of participants and the combination of data fields requested. This means that personal data would still be disclosed against the express assurances given to these patients as to the confidentiality of their sensitive, medical data. If some can self-identify it is likely that others would be able to do so in this fairly active and relatively small community. Even the fact of participation in the trial would not be fair to reveal, let alone specific health data.

There is also the question of breaking the contract of confidential treatment with trial participants from when consent was obtained, which gave assurances about what would happen to their personal data. These data were collected to be used in specified circumstances by the PACE researchers. We do not have permission to release these data in to the public domain. Given this, even if disclosure were to be deemed 'fair', we do not believe that Schedule 2, condition 6 of DPA, or any condition from Schedule 3 (which is of even greater relevance) is satisfied. QMUL thus contends that no individual-participant data can be released in to the public domain as per its arguments herein and

supported by the ICO (see cases FS50514995 and FS50484575) and the Information Tribunal in case EA/2006/0090."

37. The University went on to explain that as the release of individual data would cause it to break its specific agreement with the patients who consented to participate in the study on that basis, this would erode trust and cause people to withdraw from any future new studies that it might plan to undertake. It informed the Commissioner that it did not believe that this was mere speculation as it was aware that a previous release of information through an FOI request resulted in a participant withdrawing consent to use their data some two years after leaving the PACE trial. As a result it was required to undertake extensive and expensive recalculations.
38. In relation to the University's initial response, the Commissioner queried why the University believed that it was not possible for the information to be anonymised. He noted the its reference to the risk of risk of third party identification and the motivated intruder test but indicated that he was not convinced that there was evidence as to how the motivated intruder could actually identify the individuals in question. He asked the University to provide some further explanation as to what means it believed were reasonably likely to be available to the motivated intruder to facilitate re-identification of the participants in the PACE trial.
39. With regard to possible self-identification the University explained that:

"Firstly, each participant would know which arm of the trial to which they had been allocated, so this would bring identification down to about 1 in 160. After this, they are likely to know in particular how far they were able to walk (or if they were able to walk at all) in the 6 minute walking test both at baseline and at 52-week follow up. So this pair of figures should be enough but each participant would also have an idea of their Chalder Fatigue score at least, which was determined by a self-completed questionnaire; they would know, as can be seen from the data, what is a high score and what is low and could correlate this to other scores relating to themselves. Some of the participants have identified themselves in public as having taken part in the trial, either online or by speaking to the press. Therefore, there is at least some information in the public domain to assist further identification."
40. The University confirmed that the requested data had been obtained from participants filling in questionnaires, answering questions verbally or undertaking a test (e.g. walking test). As all these data were taken and/or derived from participants, it believed that they would be aware of their answers, particularly when they scored very high or very low on

certain measures, or when they declined to take a test, such as the walking test, due to being unwell.

41. In relation to a motivated intruder being able facilitate re-identification of participants, the University argued that:

"The PACE trial has been subject to extreme scrutiny and opponents have been against it for several years. There has been a concerted effort by a vocal minority whose views as to the causes and treatment of CFS/ME do not comport with the PACE trial and who, it is QMUL's belief, are trying to discredit the trial. Indeed, as noted by the editor of the Lancet, after the 2011 paper's publication, the nature of this comprised not a 'scientific debate' but an "orchestrated response trying to undermine the credibility of the study from patient groups [and]... also the credibility of the investigators and that's what I think is one of the other alarming aspects of this. This isn't a purely scientific debate; this is going to the heart of the integrity of the scientists who conducted this study." (Health Report, Comparison of treatments for chronic fatigue syndrome - the PACE trial (National Radio, Australian Broadcast Company April 18, 2011) interview of Richard Horton and Michael Sharpe). Further, in this interview Michael Sharpe, a Co-Principal Investigator of the trial, states

"I think the first thing to say here is that we recruited 640 patients into this trial and there wasn't a high rate of refusal of taking part in the trial and those patients remarkably, a vast majority of them stayed right through to the end of the trial, they accepted the treatments and they completed our outcome data. So I think it's very important to remember that if you go out there to the clinics that most patients with chronic fatigue syndrome, all they want is the evidence for what they have to do. There is parallel to that, a very vociferous series of websites and so on, it's not really the same world as the ordinary patient coming to the clinic. They have been quite hostile in many ways to the findings of the trial and unfortunately also to the people who've undertaken the trial and collaborated with the trial,"

and Richard Horton comments,

"I think this is where one sees a real fracture in the patient community. One is seeing a very substantial number of patients very willing to engage in this study, desperate to get good evidence on which to base their future treatment but one sees a fairly small, but highly organised, very vocal and very damaging group of individuals who have I would say actually hijacked this

agenda and distorted the debate so that it actually harms the overwhelming majority of patients,”.

This community actively seeks to identify and attack those who are associated with the PACE trial.”

42. The University went on to indicate that it believed that anonymisation was no longer as secure as perhaps once assumed. It stated that:

"This quote is taken from Paul Ohm, Broken Promises of Privacy: Responding to the Surprising Failure of Anonymization, 57 UCLA L Rev 1701 (2010):

"In the European Union, the famously privacy-protective Data Protection Directive extends a similar safe harbor through the way it defines 'personal data.' Yet reidentification science exposes the underlying promise made by these laws—that anonymization protects privacy—as an empty one, as broken as the technologists' promises. At the very least, lawmakers must reexamine every privacy law, asking whether the power of reidentification and fragility of anonymization have thwarted their original designs. The power of reidentification also transforms the public policy debate over information privacy. Today, this debate centers almost entirely on squabbles over magical phrases like 'personally identifiable information' (PII) or 'personal data.' Advances in reidentification expose how thoroughly these phrases miss the point. Although it is true that a malicious adversary can use PII such as a name or social security number to link data to identity, as it turns out, the adversary can do the same thing using information that nobody would classify as personally identifiable.”

The information that has been requested will be put on a public website and picked through. Persons whose hostility to those who participated in the trial and supported it has been noted. Clearly it cannot be said that there is no risk of such motivation to re-identify these patients. If this happens it will have implications for other research and could damage our ability to attract research participants and conduct research, which is one of our key missions, as with all universities. This cannot be said to be in the public interest.”

43. The Commissioner then wrote another letter to the University in which he raised further concerns, based on the evidence available to him, as to the applicability of section 40(2) to the withheld information.

44. The University informed the Commissioner that there were further factors which it wished to raise and highlight for consideration. It pointed to a previous decision (FS50514995) in which the Commissioner had upheld the application of section 40(2) to a request for primary outcome measure scores.

45. The University went on to explain that:

"... the information sought here remains the sensitive medical information of 640 patients, who although consented to participate in a research study, received medical treatment from medical practitioners subject to obligations of confidence and as QMUL has further noted, their participation in the study was subject to specific assurances of confidentiality, raising clear expectations, reasonably held, that such information would be kept private. A disclosure without consent of the patients' medical data would seem to breach both data protection, the medical obligation of confidence and Article 8 ECHR."

46. The University stated that it did not believe that the data could be safely anonymised. In its view:

"This is not aggregate data such as in Department of Health v IC [2011] EWHC 1430 but, rather, individual level data which by its very nature "are much more likely to reveal an individual's identity than aggregate data", a risk that increases as the number of data items increases and with the number of individual-level records (see HSCIC Anonymisation Standard (2013)). Self-identification from the published results at the eleven individual level data fields (at baseline and conclusion for some), is at the very least, a likely outcome. As has been noted in the context of health data where the boundaries are not clear between non-personal data (due to anonymisation) and personal data, that the risk of identification rises under the FOIA as one must assume some motivation to publish and identify as the data must be released without conditions, a risk considered equivalent to that of data published publicly by the data controller on a public website (see M. Oswald, Anonymisation Standard for Publishing Health and Social Care Data, Supporting Guidance: Drawing the line between identifying and non-identifying data (NHS 2013)). The NHS guidance further indicates that even where the data is of limited interest topically (such as the example of local council ingrown toe nails patients) "where published data are freely available to anyone, even the lowest risk publication carries significant risk."

47. The University believed that the Commissioner:

"...must further consider this greater risk presented for identification with this data set from the highly motivated requestor who will likely publish it on a CFS/ME group website, such as Phoenix Rising, where it will be available to all CFS/ME activists seeking to discredit the PACE trial and its researchers, as has been demonstrated, since they do not agree with the PACE trial outcomes. The risk is maximised by the fact that the CFS/ME patient community is a very small percentage of the population (e.g. estimates at less than 1%) and the PACE trial population already known to be part of that is relatively large and possibly including members of the above. The risk that additional information could be combined with the individual level data to allow identification must be considered not at all far-fetched, although QMUL need not be expected to know exactly what additional information there is presently. See e.g., Voyias v IC and London Borough of Camden, EA/2013/0003."

48. The University further noted that:

"...were this same data from medical treatment held in databases under the NHS, even to process it for anonymisation would usually require consent (see NRES Guidance on Research Database Applications (September 2010)). This is where the public good will benefit from such access for medical research or improved patient care purposes requiring applications with proper planning for security and subject to further obligations of confidentiality as well as ethical review of its use the norm. Without such consent, access to medical treatment databases for research must comply with the Health Service (Control of Patient Information) Regulations 2002 that establish the circumstances for the lawful processing of confidential patient information, despite any obligation of confidence that may be owed; these establish circumstances for the common law duty of confidence to be set aside for particular medical purposes. These processes include, for research, ethical approval as well as specific evaluation by the Confidentiality Advice Group of the public interests requiring a statement of the tangible benefits from such medical research to counter the "potential damage to patient care that might follow a loss of trust in the confidentiality of the information held by providers of healthcare services" and to protect, on balance, "...the public good in a health care service which holds and processes patient information confidentially" (see NHS National Research Authority Principles of Advice: Exploring the concepts of 'Public Interest' and 'Reasonably Practicable', pp. 2-3 (April 2013)). Such uses are further subject

to limitations on processing to those strictly necessary for such research and to persons essential to that processing, subject to equivalent obligations of confidence, with controls for unauthorised access and reviews as to the processing's continued necessity (see NRES Guidance, generally). Where data is anonymised but even a very slight risk of identification exists, the data cannot be released without appropriate controls."

49. The University raised concerns that any release of the PACE medical treatment data under FOIA would be without any limitation. It went on to argue that:

"There would be no controls on ethical use, access, security, continued obligations of confidence or its further processing of any kind. Although transparency is recognised as a public interest in itself, it is hard to fathom that while such controls and limitations are necessary to further the public interest in continuing medical research or improved patient care in order for such sensitive patient medical data at even slight risk of identification to be released under the above regime, that transparency alone would justify that the virtually identical medical treatment data, held outside the NHS due to its compilation for such research, warrants no such considerations of risk. Indeed, not only is there not the compelling interest of such further valuable medical research or care here, but also, as recognised by the ICO, the request is merely one of a series of requests for similar access to this same medical treatment information, upheld by the ICO on several occasions, including a request by the complainant found vexatious (see FS50558352) as part of a campaign by a small group of CF/MSE activists to discredit research and researchers whose results they do not agree with. There is a risk of identification of individuals and a breach of the patients' expected reasonable expectations of confidentiality in light of their consents to participate in PACE in reliance on non-disclosure except to limited practitioners and researchers.

The Commissioner's view

50. The Commissioner notes that the withheld information contains a row for each of the 640 participants in the PACE trial. Each row contains 14 columns. The first column contains the personal pin number for each participant. The remaining columns contain numbers which represent the outcomes of various tests related to the participant. The University informed the Commissioner that this information was obtained from participants filling in questionnaires, answering questions verbally or undertaking a test (for example a walking test). There are a range of

potential scores for each column with the results for some columns having wider ranges of scores than other columns.

51. The Commissioner recognises the need for a great deal of caution in this area. He acknowledges the sensitivities over the release of a significant amount of data connected with people's health in to the public domain and the care that needs to be taken to try to ensure that it is not possible to link any of that data to specific individuals.

52. The ICO's Code of Practice on Anonymisation 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." (Page 16)

53. In relation to the issue of identifiability the ICO's guidance "What is personal data" states:

"Sometimes it is not immediately obvious whether an individual can be identified or not, for example, when someone holds information where the names and other identifiers have been removed. In these cases, Recital 26 of the [European Data Protection] Directive states that, whether or not the individual is nevertheless identifiable will depend on "all the means likely reasonably to be used either by the controller or by any other person to identify the said person".

Therefore, the fact that there is a very slight hypothetical possibility that someone might be able to reconstruct the data in such a way that the data subject is identified is not sufficient to make the individual identifiable for the purposes of the Directive. The person processing the data must consider all the factors at stake." (Page 8)

54. The Code of Practice notes that neither the DPA or FOIA provide any practical help to organisations to determine whether the release of anonymised data is likely to result in the re-identification of an individual or whether anyone would have the motivation to carry out re-identification.

55. However, it goes on to state that :

"However a useful test – and one used by the Information Commissioner and the Tribunal that hears DPA and FOIA appeals – involves considering whether an 'intruder' would be able to achieve re-identification if motivated to attempt this.

The 'motivated intruder' is taken to be a person who starts without any prior knowledge but who wishes to identify the individual from whose personal data the anonymised data has been derived. This test is meant to assess whether the motivated intruder would be successful.

The approach assumes that the 'motivated intruder' is reasonably competent, has access to resources such as the internet, libraries, and all public documents, and would employ investigative techniques such as making enquiries of people who may have additional knowledge of the identity of the data subject or advertising for anyone with information to come forward. The 'motivated intruder' is not assumed to have any specialist knowledge such as computer hacking skills, or to have access to specialist equipment or to resort to criminality such as burglary, to gain access to data that is kept securely." (Pages 22-23)

56. The Commissioner notes that the complainant had specifically stated in his request that he did not require the University to provide the participant's ID numbers if it deemed it inappropriate to disclose this information. Consequently, he would not regard this information as falling within the scope of the complaint and not therefore a matter on which he needs to make a decision.
57. As part of its arguments in relation to the application of section 40(2), the University has contended that, given the nature of the information and the number of participants in the PACE clinical trial, there is a significant risks of self-identification by participants if the withheld information were to be released. Whilst the Commissioner acknowledges the possibility that some individuals may be able to identify themselves in the withheld information, he does not believe that this is sufficient for those individuals to be identifiable for the purposes of section 40(2). In his view, for an individual to be identifiable under section 40(2), it must be reasonably likely that another person can identify them from that information and other information that may be available to them.
58. The Commissioner notes that the University has referred to the risk of third party identification and the motivated intruder test. However, it has not provided any evidence as to how the motivated intruder might be able to actually identify participants from the trial from the information contained in the requested information and other information that may be available to such an individual. There is no indication in the University's submissions to the Commissioner as to what means are reasonably likely to be available to the motivated intruder to facilitate re-identification.

59. As part of its arguments, the University has referred to a previous decision of the Commissioner (FS50514995 issued on 23 January 2013)) in which the he upheld the application of section 40(2) to a request for primary outcome measure scores from the PACE trial. In his decision the Commissioner referred to the issue of prior knowledge and re-identification.

60. The Code of Practice on Anonymisation states that:

"Re-identification problems can arise where one individual or group of individuals already knows a great deal about another individual, for example a family member, colleague, doctor, teacher or other professional. These individuals may be able to determine that anonymised data relates to a particular individual, even though an 'ordinary' member of the public or an organisation would not be able to do this." (Pages 24-25)

61. In his decision, the Commissioner specifically refers to the part of the Code which says that it is good practice when releasing anonymised data to try to assess:

"...the likelihood of individuals having and using the prior knowledge necessary to facilitate re-identification. It is accepted that this will be difficult to conduct on a record by record basis for large datasets or collections of information. It will often be acceptable to make a more general assessment of the risk of prior knowledge leading to identification, for at least some individuals recorded in the information and then make a global decision about the information; the chances that those who might be able to re-identify are likely to seek out or come across the relevant data;" (Page 25)

62. It goes on to state that:

"It is reasonable to conclude that professionals (such as doctors) with prior knowledge are not to be likely to be motivated intruders, if it is clear their profession imposes confidentiality rules and requires ethical conduct." (page 25)

63. The Commissioner notes that the request considered in FS50514995 asked that each set of information should be similarly correlated by, for example, recruitment date or random participant number assignment. The University commented in that case that if, for example, one knew the randomised date, coupled with other information, an individual could identify a participant and their outcome scores. It explained by way of illustration that in April 2007 there were only 12 patients randomised which was only a small percentage of the total number of patients who

took part in the trial. As a consequence it believed that identification would be possible if this type of information were placed in the public domain in combination with the medical data requested.

64. The Commissioner notes that, in this case, the requester has not asked that the medical data that he has requested be ordered or grouped in any way which might provide assistance to anyone seeking to identify the participants. He has only asked that each row of results relates to the same participant.
65. The Commissioner further notes that the Code of Practice on Anonymisation states that:

"Data protection law is concerned with information that identifies an individual. This implies a degree of certainty that information is about one person and not another. Identification involves more than making an educated guess that information is about someone; the guess could be wrong. The possibility of making an educated guess about an individual's identity may present a privacy risk but not a data protection one because no personal data has been disclosed to the guesser. Even where a guess based on anonymised data turns out to be correct, this does not mean that a disclosure of personal data has taken place." (Page 26)

66. It is not clear to the Commissioner what prior knowledge an individual might have which might allow them to identify one or more of the participants in the PACE trial from the information requested, particularly given the large number of participants. In addition, he is not convinced that there is a sufficient basis for him to determine that it might be possible for a motivated intruder to identify any of the participants in the trial. Consequently, he has decided that the withheld information does not constitute personal data and that the exemption in section 40(2) is not applicable.

Section 41 – Information provided under a duty of confidence

67. Section 41 of FOIA provides that:

"Information is exempt information if-

(a) it was obtained by the public authority from any other person (including another public authority), and

(b) the disclosure of the information to the public (otherwise than under this Act) by the public authority holding it would constitute a breach of confidence actionable by that or any other person."

(a) Was the withheld information obtained by the University from another person?

68. The University explained that the third parties from which the information in question derived were all the participants in the PACE trial. The data was supplied to it in the course of a clinical trial to be used only as spelt out in the consent forms signed by each patient.
69. The Commissioner has therefore concluded that the information contained in the withheld reports was obtained by the University from another person, the participants in the trial, for the purposes of section 41. He went on to consider whether disclosure would constitute an actionable breach of confidence.

(b) Would disclosure of the withheld information constitute an actionable breach of confidence?

70. In order to determine whether disclosure would constitute an actionable breach of confidence the Commissioner considered the following questions:

(i) Does the withheld information possess the necessary quality of confidence?

(ii) Was the withheld information imparted in circumstances importing an obligation of confidence?

(iii) Would unauthorised disclosure cause a detriment to the party providing the information or to another party?

(iv) If parts (i)-(iii) are satisfied, would the public authority nevertheless have a defence to a claim for breach of confidence based on the public interest in the disclosure of the withheld information?

71. The University argued that, as medical information, the withheld information was of the kind which was certainly of importance to the confider and certainly not trivial. It related to an illness to which a certain amount of social stigma was attached. It believed that it had the necessary quality of confidence under the traditional tests of confidence under *Coco v Clarke* [1969] *RPC 41* as it was disclosed in the context of a confidential relationship, under a clear obligation of confidence.
72. The University went on to explain to the Commissioner that the information was supplied not only under a traditional doctor-patient relationship, which obliges information to be kept confidential (see generally, General Medical Council, 'Confidentiality' (2009)), but also in the course of a clinical trial. Such trials were required for ethical reasons

to gather explicit consent from all participants. The University explained that the consent forms gave clear assurances about confidentiality and what would happen to each individual's data, which would be directly contravened if this information was released. It therefore believed that there was both an implied obligation of confidence and an explicit written guarantee.

73. The University argued that disclosure would cause a detriment to both the trial participants in question and to the University itself. In relation to the trial participants, it believed that, as it had previously explained, the information was sensitive personal data relating to a medical condition. If the participants were to be identified as either suffering from CFS/ME or having taken part in the trial, it would cause them damage and distress.
74. In relation to the detriment to the University itself, it believed that releasing data in violation of the Data Protection Act and contrary to the funder's policies would be likely to compromise its ability to attract research funding from sponsors and deter individuals from participating in future medical trials if their personal data could not be guaranteed to be kept confidential or anonymous.

The Commissioner's view

75. In order for section 41 to apply it is necessary for all of the relevant elements of the test of confidence to be satisfied. Therefore if one or more of the elements is not satisfied then section 41 will not apply. The Commissioner has explained, in relation to the application of section 40(2), why he does not consider it possible to reliably identify an individual as the subject of the withheld information from its contents or if it is linked with other material available to the general public. In such circumstances he does not consider that there can be an expectation of confidence or that disclosure would cause detriment by way of an invasion of privacy. Therefore it follows that there can be no breach of confidence to action and section 41 does not apply.

Section 43(2) – Prejudice to commercial interests

76. Section 43(2) provides that information is exempt if its disclosure would, or would be likely to, prejudice the commercial interests of any person.
77. The University argued that disclosure of the information withheld under section 43(2) would be likely to prejudice its commercial interests.

Engagement of section 43(2)

78. The Commissioner initially considered whether the relevant criteria for the engagement of section 43(2) were satisfied.

The University's arguments

79. The University informed the Commissioner that it believed that section 43(2) applied to the withheld information as disclosure would be likely to prejudice its commercial interests because it might affect its ability to conduct research and attract the necessary funding to carry this out. It believed that this would have a knock-on effect of damaging its reputation and thus its ability to recruit high quality staff and students, which would also affect funding from both tuition fees and from the Research Excellence Framework, participation in which would be adversely affected as a further consequence.
80. The University explained that it believed that releasing the requested data would be likely to affect the research it was able to conduct, particularly with human participants who had to be recruited, if a disclosure of their sensitive personal data at the individual level set a precedent.
81. The Commissioner was informed by the University that the PACE trial closed to recruitment in 2009 and follow up continued until mid-2012. It indicated that analysis of the data continues to this day and papers continue to be published (for example, one paper in press provides the results of the follow-up up to 2012).
82. The University stated that the patient participants of the original study gave informed consent to their participation based on explicit assurances that the research data collected during their assessment and treatment would remain confidential and used only for research purposes (i.e. not released to any member of the public that asked for it). It believed that the failure of investigators to honour this explicit agreement and the participants' consent conditions, not to release any of these medical data to other than to qualified researchers, would be likely to undermine their continuing trust in investigators' representations. Specifically, if these data were to be released publicly without limitation, it would clearly signal that any future sensitive data collected during a follow-up study could similarly be at risk of disclosure, despite any assurances investigators might make. In the University's view, this would be likely to discourage participants from participating in any follow-up study that it might decide to undertake and future medical research studies involving CFS/ME in which they might be invited to participate.
83. The University believed that the publicity surrounding the disclosure that would occur if the requested information were to be released would cause anxiety to those who participated that they would be identified. In addition, the possible pressure and hostility to participants who might be identified from the disclosure, which it believed was not a remote

possibility, would be very likely to deter these former participants from participating in any follow up studies.

84. The University explained that the ME/CFS patient representatives involved in the trial oversight did so only based on assurances that their identities would not be known so as not to incur pressure and hostility. Moreover, participants' lack of trust had been found to be one of the participant-related factors among the considerable difficulties to recruiting suitable participants for all clinical trials. (See 'Recruitment Challenges in Clinical Trials for Different Diseases and Conditions' in Public Engagement and Clinical Trials: New Models and Disruptive Technologies: Workshop Summary (Institute of Medicine, National Academies Press 2012)).
85. In the University's view, it was, therefore, likely to be a much greater challenge to re-enrol a group for any further study where trust had already been diminished by the breach of confidence when no assurances could change the circumstances of the already released information or the significant threat of a future release from a new trial.
86. The University provided the Commissioner with details of two participants in the PACE trial who withdrew consent to the use of their data and asked for their data to be destroyed. It explained that both were linked to concerns about confidentiality. In one case, this occurred following a data release by the Strategic Health Authority, which were responsible for the Research Ethics Committee which oversaw the PACE trial. Following an FOIA request, the Strategic Health Authority released all the data and files that the University had submitted to the Research Ethics Committee over the years, which included not only the original protocol, but all amendments, and all other relevant documents, such as the details of all 50 or so serious adverse events and reactions recorded during the trial up until the point of release. This amounted to some 600 pages of material.
87. The University informed the Commissioner that as a result of the individual's withdrawal, the investigators had to remove all relevant data and restart the main analysis, delaying progress by four months, with consequent increased costs caused by extended employment of relevant staff. It also resulted in a delay in the publication of the results in publicly available peer-reviewed journals.
88. In the other case, the University informed the Commissioner that the withdrawal was linked to concerns about confidential data being used by researchers and other people, even in an anonymised form. The University contended that, although it could not make a direct link to a data release in this case, it did not take much imagination to conclude that news of any PACE data being released, following an FOIA request,

would have had a detrimental effect on this ex-participant, and may have led to, or encouraged, them to request that all their data be destroyed.

89. The University believed that similar patient sensitivity could be expected in future if the withheld information were disclosed. Beyond this, it had serious concerns over the potential consequence of it not being able to enrol future study participants on a timely basis in light of the reluctance of participants to participate as borne out in the above trial recruitment research.
90. In the University's view, the specific public interest in favour of not disclosing this patient information was that it would foster the ability to conduct continued research in this area, including any future research study which might include the same participants from the PACE trial. It pointed out that such large scale, long term studies were rare, so the potential that one could be viable was significant.
91. The University explained that the participants in the PACE trial gave consent to participate and have their sensitive data used for this medical research based on the written, express assurances by trial investigators in the PACE trial's consent forms of the research data's confidentiality with clear explanations that such would only otherwise be accessible to qualified researchers. It contended that disclosure to the general public of the withheld information would mean that there could be no expectations that participating in a clinical trial would not lead to their future data being released into the public domain, without their consent. Indeed, the investigators believed rather that they would have to call this possibility to their attention.
92. The University was of the view that the diminished trust and enhanced potential exposure increase the likelihood that participants would refuse participation in further research or that it would significantly increase the time, effort and cost to get them to enrols. The University pointed to the above mentioned clinical trial research which had noted that *"patients worry about a great number of issues, their health being only one of them, and every aspect of a trial protocol that makes it harder to understand, less relevant to them, and less convenient diminishes the likelihood of participation."*
93. The University informed the Commissioner that the fewer participants who enrolled for a study affected the organisation and validity of the study and its findings and, indeed, as this same research indicated, the potential viability of a study and with it the reputation of investigators and research institutions. It pointed to the following statement in the research:

"From an institutional and investigator perspective, not meeting enrolment numbers in a timely way can cause a clinical trial to lose momentum and can lead to other negative conditions such as investigator burnout. In the worst cases, low enrolment can cause a trial to be abandoned—a costly outcome that can harm the credibility of individual investigators and their institutions. The public and private organizations that fund trials look to a researcher's and an institution's prior history when making grant awards, and they take notice when investigators fail to meet their anticipated enrolment goals. From the investigator's perspective, then, patient recruitment is a significant responsibility and not doing it effectively may lead to frustration, institutional concern, and even embarrassment."

94. The University believed that the release of patient results under FOIA might also have wider repercussions on other studies, whether at QMUL or beyond, and that such an impact on research was not in the public interest.
95. The University went on to argue that disclosure of the withheld information could impact on its future funding. It explained that:

"QMUL's ability to attract research funding could also be hindered. This would again have implications for damaging QMUL objectives, which is not in the public interest, but equally, as we have stated in previous FOI refusals (though on unrelated topics) anything that imperils our finances we would consider to be exempt under s.43(2) in that it would be likely to damage our commercial interests. Queen Mary competes with other HEIs in an increasingly competitive market, especially with regards to the recruitment of students and attracting research funding. Securing of research grants takes place in a competitive market. In order to meet its strategic objectives related to knowledge creation and dissemination, by providing high quality education and carrying out high quality research, Queen Mary must be able to rely on the revenue stream from research it carries out. In financially tough times and while receiving less and less from the public purse, Queen Mary needs to protect all sources of income. In order to thrive and meet its objectives, Queen Mary must be able to protect its position, compete and raise funding from all possible sources. Certain disclosures under FOI which might impact on this cannot be said to be in the public interest on balance in that this would be likely to prejudice our commercial interests"

The Commissioner's view

(i) Applicable interest within the exemption

96. The Commissioner considered whether the prejudice claimed by the University is relevant to section 43(2). The Commissioner is satisfied, in light of the University's arguments that the potential prejudice that it has identified relates to its commercial interests.

(ii) The nature of the prejudice

97. The Commissioner next went on to consider whether the prejudice being claimed was "real, actual or of substance" ie not trivial and whether there was a causal link between disclosure and the prejudice claimed. The Commissioner is satisfied that the prejudice being claimed is not trivial or insignificant and that there is the relevant causal link.

(iii) The likelihood of prejudice

98. The University argued that the disclosure of the withheld information would be likely to prejudice its own commercial interests.

99. The Commissioner's guidance on the prejudice test states that the term "would be likely":

"...refers to a lower level of probability than 'would', but one which is still significant. This interpretation is based on the judgment of Mr Justice Munby in R (on the application of Lord) v Secretary of State for the Home Office [2003] EWHC 2073 (Admin) (a Data Protection Act case) who said:

*"Likely connotes a degree of probability that there is a very significant and weighty chance of prejudice to the identified public interests. The degree of risk must be such that there 'may very well' be prejudice to those interests, even if the risk falls short of being more probable than not."
(paragraph 100)" (para 30)*

100. This interpretation of "would be likely" was relied on by the Information Tribunal in the case of *John Connor Press Associates Limited v The Information Commissioner (EA/2005/0005)*. The Tribunal confirmed that, when determining whether prejudice would be likely to occur, the test to apply is that *"the chance of prejudice being suffered should be more than a hypothetical possibility; there must have been a real and significant risk."* (para 15). In other words, the risk of prejudice need not be more likely than not, but must be substantially more than remote.

101. The Commissioner's guidance on the prejudice test goes on to state that:

"On the basis of these judgments, 'would be likely' means that there must be more than a hypothetical or remote possibility of prejudice occurring; there must be a real and significant risk of prejudice, even though the probability of prejudice occurring is less than 50%." (para 32)

102. The Commissioner notes that the University has argued that disclosure of the withheld information would be likely to deter existing participants in the PACE trial from taking part in any follow up studies and also deter other potential participants from volunteering for such studies. It believed that this would affect its ability to carry out research and attract the necessary funding to carry it out. This in turn would damage its reputation and consequently its ability to recruit high quality staff and students with a consequent effect on its funding from tuition fees and its participation in the Research Excellence Framework.

103. As regards the University's argument that disclosure might result in existing PACE trial participants no longer being willing to participate in follow up studies and others not being willing to become involved in future similar research projects, the Commissioner accepts that this may be a possibility. He notes that the University's evidence includes details of two participants withdrawing from the PACE trial over concerns about confidentiality, one of which followed the release of data by the Strategic Health Authority. However, he not convinced that there is sufficient evidence for him to determine that the disclosure of the withheld information would be likely to lead to a sufficiently significant number of existing 640 participants withdrawing so as to affect the possibility of further viable follow up studies taking place. He is also not convinced that there is sufficient evidence for him to determine that disclosure would be likely to deter significant numbers of other potential participants from volunteering to take part in future studies so as to affect the University's ability to undertake such research. As a result, the Commissioner is reluctant to accept that disclosure of the withheld information would be likely to have an adverse effect on the University's future ability to attract necessary funding and to carry out research in this area, with a consequent effect on its reputation and ability to recruit staff and students.

104. As part of its arguments, the University has also raised concerns about the impact that may result from individual participants in the PACE trial being identified if the requested information were disclosed. As the Commissioner has previously noted in relation to his consideration of the application of section 40(2), he is not persuaded by the evidence

presented to him that it would be possible for individuals to be identified if disclosure of the requested information were to occur.

105. In light of the above, the Commissioner, is not satisfied that there is sufficient evidence for him to conclude that disclosure of the withheld information would be likely to prejudice the University's commercial interests. Consequently, he has determined that section 43(2) is not engaged.

Right of appeal

106. 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

107. 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.

108. 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

Rachael Cragg
Group Manager
Information Commissioner's Office
Wycliffe House
Water Lane
Wilmslow
Cheshire
SK9 5AF