IN THE FIRST-TIER TRIBUNAL (INFORMATION RIGHTS) EA/2015/0269

BETWEEN:

QUEEN MARY UNIVERSITY OF LONDON
(Appellant)

And

THE INFORMATION COMMISSIONER
(First Respondent)

MR ALEM MATTHEES
(Second Respondent)

ALEM MATTHEES' MAIN RESPONSE

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Part 1: Purpose and scope of this response

An introduction and summary of the issues raised in this response.

1.1) Introduction and background

This is a detailed written response to Queen Mary University of London's (“QMUL”) appeal to the First-tier Tribunal (Information Rights) [EA/2015/0269], of a decision notice issued by the Information Commissioner's Office (“ICO”) [FS50565190]. I initiated the Freedom of Information Act 2000 (“FOIA”) request under dispute. An introductory summary of the PACE trial, the FOIA request itself, Chronic Fatigue Syndrome (“CFS”), and Myalgic Encephalomyelitis (“ME”), has already been provided in QMUL's Notice/Grounds of Appeal, the ICO decision notice FS50565190, and the ICO's / Information Commissioner's Response.

I address the arguments in QMUL's Grounds of Appeal and FS50565190, in relation to FOIA exemptions S.22A, S40(2), S.41, S.43(2), and the Data Protection Act 1998 (“DPA”). I will describe why QMUL has failed to show that the cited exemptions apply to this FOIA request. Later I will cover the numerous issues outlined in QMUL's “Note to Tribunal on behalf of the Appellant” (topics to be covered extensively by witnesses in writing and at the hearing). I will explain why disclosure of “the disputed information” is strongly in the public interest, and how non-disclosure will prolong a controversy that is damaging QMUL's reputation and distressing patients. I will also provide context for QMUL's speculations about activism against the PACE trial. On balance of the relevant factors and probabilities, the disputed information should be disclosed. I therefore respectfully ask the Tribunal to carefully consider these arguments, reject QMUL's appeal, and uphold the previous decision made by the Information Commissioner.

A detailed written response is the best way I can fairly participate in the proceedings. The scope and length of my response is in proportion to the complexity of the numerous issues QMUL raised. Most footnotes are hyperlinks only, and some articles are referenced by their PubMed ID (PMID).

1.2) Summary of main reasons to oppose the appeal

This FOIA request asks for a careful selection of individual patient data from the PACE trial. QMUL assert that this, the disputed information, is sensitive personal data and that disclosing it to the public would breach patient confidentiality, causing damage to QMUL's reputational interests.

QMUL's arguments for applying the exemptions fundamentally depend on inaccurate assessments

that substantially exaggerate the risks of re-identification. Under the FOIA and DPA, sufficiently anonymised or de-identified data that poses no significant risk of re-identification, is not exempted as sensitive, personal, or confidential. Confidentiality guidelines from the NHS and GMC are concerned with identifiable information, and allow anonymisation without consent. The trial consent forms do not explicitly rule out the sharing of anonymised individual patient data.

There is no significant risk of re-identification from the disputed information by itself, and the information required to enable re-identification by cross-referencing is securely held. QMUL has not provided evidence of a plausible mechanism of re-identification. Cases where anonymisation failed have involved factors that do not apply here, as the disputed information does not include any direct or indirect personal identifiers, does not contain uniquely rare values, and does not involve a vast number of variables. Disclosure is fair, lawful, and will not harm data subjects; nor will it be an actionable breach of confidence. Investigators of the FINE trial (sister to PACE and both funded by the Medical Research Council) voluntarily published similar individual patient data while meeting data sharing policies for anonymity and confidentiality.

The balance of public interests strongly favours disclosure. Previous reports of the PACE trial results were undermined by highly contentious deviations from the published trial protocol, with some post-trial endpoint changes that were significantly flawed and poorly or erroneously justified. This led to misleading conclusions and inaccurate media coverage, causing patients distress and exposing them to adverse consequences from unrealistic expectations to improve with treatment. QMUL has not sufficiently acknowledged or addressed these concerns, and failed their responsibility to provide complete, accurate, and meaningful reports on recovery from CFS. Valid questions and criticism of the PACE trial have been expressed by academics, researchers, scientists, journalists, patients and advocates with various backgrounds or qualifications. QMUL has largely misrepresented the arguments, beliefs, and motives of those who express such concerns.

The trend in the wider research community is increased transparency and open data, which for some supporters includes public access to individual patient data while protecting patient privacy. The longstanding and escalating controversy over the PACE trial results will be mostly resolved by disclosing the disputed information. This will enable correction of errors, encourage debate, and allow independent re-analysis of trial results in a transparent or open (publicly verifiable) manner.

1.3) Purpose and goals of disclosing the disputed information

a) To overcome the breakdown of trust between QMUL and the public (exacerbated by contentious protocol deviations, exaggeration of results in the press, and the failure to address these concerns). It is very important that the controversy over the PACE trial results is promptly resolved, and the best method to help restore trust is to provide open public access to the requested data.

b) The need to examine “recovery” using the thresholds of the published trial protocol before major and questionable changes (such as he revised recovery criteria overlapping with trial eligibility criteria for severe and disabling fatigue). Test the sensitivity of various thresholds. Provide summary statistics and compare with normative population samples.

c) To conduct intention-to-treat analyses of the primary outcome measures as established in the published trial protocol in March 2007. Compare with the per-protocol, post-hoc revisions.

d) The need to understand whether the subjective questionnaire scores are correlated with more

objective measures of function, hence the inclusion of walking test distance data.

e) If there are potential concerns about post-disclosure data integrity, QMUL can consider an online data repository, or release a secure checksum or strong cryptographic hash function so that file verification software can confirm the integrity of the dataset.

1.4) Clarification for one of the data fields requested

If the disputed information is disclosed, I need to clarify one of the variables: *"Oxford criteria CFS caseness (does participant meet criteria, yes or no) [52-week followup only]"*.

It is important that this is supplied as the Oxford CFS criteria is used in the clinic i.e. stand alone without being combined with the ad hoc thresholds added on later in the trial i.e. CFQ (bimodal) score for fatigue and SF-36 score for physical function. These thresholds were not mentioned in this manner in the original trial protocol, and would have made the Oxford CFS criteria completely redundant in the original recovery criteria (as more stringent thresholds were also a part of the original recovery criteria). The 2011 Lancet publication further indicates that the Oxford CFS criteria could be met despite failing trial entry criteria for fatigue and physical function.

Part 2: Response to exemption S.40(2) [sensitive personal data]

This is a response to QMUL's First Ground of Appeal: Section 40(2).

2.1) Sufficiently anonymised or de-identified data is not personal

De-identification has fundamental implications for the applicability of the FOIA and DPA. There are multiple methods of "anonymisation", and distinctions are not always made in guidelines. In my previous correspondence with QMUL, I mostly referred to anonymisation in general. This FOIA request involves a heavily redacted dataset with most variables removed, or a selection of trial data which has undergone de-identification, and ceases to be personal data at the point of disclosure, even though it is still personal data in the hands of QMUL (as long as it holds the other information necessary to enable identification). There is a technical difference between aggregated statistics and de-identified individual level data, but the deciding principle is the same i.e. whether disclosure of the disputed information in the requested form can lead to re-identification. QMUL mentioned pseudonymisation (replacing sensitive fields with meaningless pseudonyms), but my request for only the selected data variables implies that pseudonyms have been removed, although in keeping with the wider definition, each variable will remain linked to other variables.

In my previous correspondence with QMUL and for this response I have relied on the ICO guideline titled 'Anonymisation: managing data protection risk code of practice'. [1] Accordingly:

The anonymisation of personal data is possible, protects the privacy of data subjects, and can serve society's information needs. The DPA should not prevent the anonymisation of personal data for fulfilling FOIA requests. Anonymised data can be released without breaching the DPA, because the principles of data protection law do not apply to data rendered sufficiently anonymous that the data subject is no longer at significant risk of being identified when the data is disclosed. The definition of personal data in the DPA is based on the identification or likely identification of an individual,

1. http://ico.org.uk/for_organisations/data_protection/topic_guides/anonymisation

rather than the mere possibility of an individual being identifiable, and does not extend to cover situations where the data does not identify individuals. For data to be classed as personal under the DPA, the risk of identification must be greater than remote and be reasonably likely. The pseudonymisation of individual patient data requires more care than anonymisation techniques used to produce aggregated information or summary statistics, but this does not pose an insurmountable problem for the DPA or the FOIA. Effective anonymisation essentially means that the production or publication of the data will have no significant adverse effect on the data subjects. Consent is generally not needed to legitimise an anonymisation process, and fewer legal restrictions apply to this anonymised data. Anonymisation allows the use of data in new and different ways because the DPA's purpose-limitation rules do not apply to it.

Similarly, the Ministry of Justice guidance on S.40 of the FOIA exemptions (also in relation to the DPA principles) states that the requirements of the FOIA and DPA can be satisfied by redaction of personal information such as names. [2] The Universities UK website hosts a document providing guidance for the higher education sector, which states that S.40 does not apply to data from research projects when personal data has been effectively anonymised. [3] The EU Data Protection Directive does not apply to data that is not directly of indirectly identifiable. [4]

2.2) A key factor is whether there is a significant risk of re-identification

The probability of re-identification is a crucial point for evaluating this FOIA request, because QMUL's argument for classifying the disputed information as "sensitive personal data" is fundamentally dependent on the (allegedly) significant risk of re-identification.

According to the ICO's Knowledge Base on FOI Policy with reference to the DPA: [5] *"The test of whether the information is truly anonymised is whether on the balance of probabilities, a (or any) member of the public can identify individuals by cross-referencing the 'anonymised' data with information or knowledge already available to the public. Whether this 'cross-referencing' is possible is a question of fact based on the circumstances of the specific case."*

With particular relevance to the S.40 exemption of the FOIA, the question for the Tribunal in Beckles v IC (16 Sept 2011, EA/2011/0073 & 0074), was *"whether the individual(s) would be identifiable by members of the public, not armed with the further information held by the University [i.e. the data controller], if the data were disclosed in the form proposed."* [6]

It is therefore important to consider whether such anonymised data is likely to result in the re-identification of individuals, and whether anyone would have access to additional information and the motivation to attempt re-identification. The various guidelines on the FOIA and DPA often discuss risk assessments, which are not always simple or easy.

2.3) The disputed information does not contain any personal identifiers

Here is a hypothetical example of what a single row of the disputed information would consist of in a simple spreadsheet format as requested: 45, 55, 30, 28, 11, 10, Yes, 3, 2, 398, 403, SMC.

In 2012, the Royal Society released a report into science as an open enterprise, which raised concerns with assumptions that the privacy of data subjects could be protected by anonymisation.

2. http://www.justice.gov.uk/downloads/information-access-rights/foi/foi-exemption-s40.pdf
3. http://www.universitiesuk.ac.uk/highereducation/Documents/2013/IPBillBriefingAnnex1.pdf
4. http://ec.europa.eu/justice/data-protection/
5. http://ico.org.uk/foikb/PolicyLines/FOIPolicyPersonaldata-anonymisedstatistics.htm
6. http://www.informationtribunal.gov.uk/DBFiles/Decision/i565/20110907%20%20Decision%20%20EA20110073%20&%200074.pdf

The report highlights an example of where two separate databases were acquired and individuals could be identified with cross-referencing the two. This was made possible because both databases consisted of direct and indirect identifiers such as ZIP code, birth date, and gender. [7] Other cases of broken anonymisation or successful re-identification attacks have similarly involved multiple identifiers, such as age, location, date or type of specific event, gender, and ethnicity. [8]

A similar conclusion emerges from the document that QMUL relied upon to argue to the ICO that anonymisation was no longer as secure as perhaps once assumed (Paul Ohm's “Broken Promises of Privacy: Responding to the Surprising Failure of Anonymization” [9]). Examples of defeated anonymisation involved ZIP code, gender, birth date, unique identification numbers (or other unique information such as specific queries from individuals), or a vast number of data variables which created a unique data fingerprint that could be linked with additional information.

My FOIA request does not ask for identifiers, uniquely rare scores, or a vast number of variables. A comprehensive list of direct and indirect identifiers is provided by Hrynaszkiewicz et al. (2010) in their article on how to prepare raw clinical trial data for publication (guidance for journal editors, authors, and peer reviewers); the disputed information does not contain any of those listed, while caution is recommended when “datasets contain three or more indirect identifiers”. [10] The highly respected and very popular Public Library of Science (PLOS) publisher now uses that article as guidance for preparing trial datasets for public access. [11] (Their main journal, PLOS One, is the world's largest, with thousands of publications yearly.) A highly relevant example is covered in Part 2.8 under “FINE trial investigators have published similar individual patient data”.

In response to a BMJ policy change, Professor Peter White (lead investigator of the PACE trial) questioned whether it is *“sensible to go so far as to encourage authors of all BMJ papers to share their datasets publicly”*, citing concerns over patient confidentiality, and questioned whether data is truly anonymous when details of age, gender and locality are linked to medical histories. [12] Again, the disputed information does not contain any such identifiers.

The disputed information does not contain any uniquely personal direct identifiers e.g. name, address, National Insurance Number, biological data such as genetic information, or any other information specific to objectively identifiable information about an individual. It does not contain any indirect identifiers or clues which clearly narrow down the identification of participants e.g. age, gender, recruitment date, or participant number assignment. It does not contain qualitative or descriptive personal information e.g. written accounts of personal opinions, voice recordings, identifiable contextual experiences about personal lives, or the handwriting of living individuals.

The disputed information is generic and based on simple, quantitative, categorical, or non-unique outcomes which are either subjective, variable (fluctuations over time), or very difficult to repeat precisely (e.g. walking test). Most of the disputed information is already summarised i.e. one step removed from the information provided by trial participants; where the scores are calculated from multi-choice questionnaires, do not provide information to identify any individual, and are summarised in a manner which makes reliable extrapolation highly unlikely.

7. https://royalsociety.org/policy/projects/science-public-enterprise/Report
8. http://www.bmj.com/content/350/bmj.h1139
9. http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1450006 UCLA Law Review, Vol. 57, p. 1701, 2010.
10. http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2813427
11. http://journals.plos.org/plosone/s/data-availability
12. http://www.bmj.com/content/346/bmj.f2961/rr/645269

For example, the SF-36 physical function subscale has 21 generic values, and the Chalder Fatigue Questionnaire has either 12 (bimodal) or 34 (Likert) depending on the scoring method. The calculation of total scores allows for numerous ways of getting the same total value. It is improbable to accurately guess or reliably extrapolate the correct answers from the summed numerical scores. It would be impossible to trace the scores back to any individual, perhaps even if the answers to the questions were fully known. Meeting the Oxford criteria for CFS is a binary or categorical outcome (based on answers on a questionnaire that is not being requested here) and will not help re-identification. The Clinical Global Impression is a simple 7-item scale which crudely rates how the patient generally feels compared to previously. The six-minute walking test distance is simply how far a participant can walk, and reveals nothing personal. The group allocation of individual participants would not significantly help re-identification either.

Similarly, the disputed information does not contain rare values which could be used to narrow down the identification of participants. The working age population in the UK is about 38 million. Estimates of the prevalence of CFS in the UK vary but is often quoted to be around 250,000. It has been asserted that the participants in the PACE trial were typical and met broad criteria for CFS. The symptoms and impairments of CFS are very common among the wider patient population, and many patients would therefore share similar scores. Fatigue (etc) and physical limitations are also common in other patient populations and the general public outside those meeting criteria for CFS. The number of participants in the trial was relatively large (n=640) and the trial was a multi-site study across the UK, which further decreases the chances of re-identification. Participants were recruited between the 18th March 2005 and the 28th November 2008 using broad CFS criteria, and outcome data collection for the 52 week follow-up period was completed in January 2010; the sensitivity or usefulness of this information for re-identification may decrease with time.

The selected variables were chosen so that the intended analyses can be conducted from the bare minimum of data required, and this is only a very small proportion of the entire dataset held. Overall, in practice, the risk of re-identification is remote or non-significant.

2.4) There is no significant risk of re-identification (the risk is remote)

The risk of re-identification is not “relatively high” as asserted in QMUL's Grounds of Appeal. The disputed information itself does not contain any personally identifiable information. There is no plausible mechanism to re-identify the participants, cross-link or match up their scores with a name or other personal identifiers, without additional information that is securely held and extremely unlikely to ever become public or come into the possession of myself or someone else's public possession in the future, as it is protected under the FOIA and DPA. There is no lawful way that members of the public, without access to secure databases, could acquire those details.

Page 63 of the unabridged “PACE trial protocol: Final version 5.0, 01.02.2006”, clearly indicates that participant identification details are stored in a separate database and/or Case Report Forms; therefore are held securely and extremely unlikely to ever come into public possession. [13] “Substantial Amendment 9.0” (7 October 2008), referring to an ancillary study using PACE data, justified not attaining additional consent from the participants because: *“Participants' details will be anonymised by the trial nurse on all documentation so that only she may identify them. Only the participant's PACE PIN number and date of assessment will be documented. [...] All data reviewed will be completely anonymous to study researchers.”* (emphasis added)

13. http://www.meactionuk.org.uk/FULL-Protocol-SEARCHABLE-version.pdf

A document on the QMUL website titled 'Research and the Data Protection and Freedom of Information Acts' [14], indicates QMUL's awareness of, and routine procedures for, ensuring that "anonymous coding (pseudo-anonymisation)" can effectively conceal the identity of data subjects.

QMUL has not adequately explained how in general, anonymous coding (pseudo-anonymisation) effectively conceals the identity of data subjects, while in the specific case of my FOIA request, the disputed information suddenly cannot be sufficiently pseudonymised. QMUL has not provided a convincing mechanism for re-identification. Similarly, the consequences of re-identification as asserted by QMUL do not apply if participants are unlikely to be identified. A mere possibility is not enough to consider a person identifiable, there must be convincing reason to assess the risk as significant and not remote. The onus is on QMUL to explain how re-identification may likely occur. QMUL repeatedly failed to provide convincing evidence to the ICO.

Below I will examine QMUL's most specific explanation so far:

In ICO decision notice FS50565190 it states (§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."*

The wording suggests that the withdrawal of consent following a FOIA request was coincidental. In QMUL's Grounds of Appeal (§28.iii), it asserts that a 'motivated intruder' could seek to link the above mentioned information with the disputed information. The other information is mostly related to the trial protocol and amendments to it; there is mention of serious adverse events and reactions recorded during the trial, but such details were also later published in the Lancet. [15] It is highly unlikely that the previously released information includes identifiable medical data, otherwise it would violate the FOIA and DPA. It is also highly unlikely that the two requests can be combined to identify individual participants: With respect to the disputed information, QMUL stated in correspondence with me that none of it is in the public domain. It is therefore unclear how the disputed information could then be reliably "cross-linked" with other public data.

I agree with the Information Commissioner's Response (§21-25) that self-identification is both difficult and irrelevant, and (§26) that the professionals who treated trial participants (i.e. doctors and therapists) are bound by a duty of confidence not to attempt re-identification, a duty which §42 of QMUL's Grounds of Appeal clearly acknowledges. I would like to add this: QMUL argued that self-identification is aided by not having done the walking test; however, there is no data on the walking test for about 28% of trial participants, making this scenario relatively common.

If additional evidence is presented by QMUL, please consider whether it actually contains specific information which facilitates public re-identification in practice (not simply vague speculation, generalised examples unlikely to happen, or an expert narrowing down possible individuals after

14. http://www.arcs.qmul.ac.uk/information_governance/dp/dpa_foi_and_research.ppt
15. http://www.thelancet.com/cms/attachment/2001013463/2003813673/mmc1.pdf

QMUL purposely provides them privately with specific clues which the public would never know). In a recent response to a very similar FOIA request, QMUL only applied S.41 and S.22A, suggesting that they may no longer believe that S.40(2) is particularly relevant. [16]

2.5) Speculative assertions about 'motivated intruders' should be tested

As implied in FS50565190 and more clearly argued in their Grounds of Appeal, QMUL argues that the disputed information could somehow be used to track down and harass trial participants. QMUL also argued that participants had assurances of confidentiality, and if the disputed information was disclosed, it would cause them anxiety or distress, more so if the participants were identified. Unfortunately, it appears that QMUL may be contributing to a climate of fear by substantially over-estimating or exaggerating the chances of re-identification, and by actively promoting the view that trial participants would be exposed to criticism and harassment if identified.

QMUL acknowledges that *"Some of the participants have identified themselves in public as having taken part in the trial, either online or by speaking to the press."* Yet QMUL has not provided any evidence that these individuals have been targeted as a result. There is evidence of the opposite (see Part 2.7 "Experiences of trial participants and their alleged views about disclosure").

Speculations about motives are usually difficult to prove, and while it is unclear what purpose re-identification would serve anyone (and to my knowledge no one has ever been arrested, charged, prosecuted or convicted of any wrongdoing in relation to the PACE trial), QMUL's speculation may at most satisfy the condition of a 'motivated intruder'. Therefore, such a test should be fairly conducted to help establish the (non-significant) risk of re-identification.

In the Case Management Note (EA/2015/0269, 11 December 2015), §10 states that the Tribunal will view a copy of the disputed information. The ICO guideline titled 'Anonymisation: managing data protection risk code of practice', contains the definition of a competent, non-specialist, non-criminal "motivated intruder" who attempts to re-identify data subjects. QMUL's claims could be tested in practice, by using the disputed information and the information alluded to by QMUL.

Any fair attempt to play the role of a 'motivated intruder' here would most likely fail. In the highly unlikely event that the Tribunal is able to identify individual participants, this could unfortunately suggest that a significant data security breach or administrative error has previously taken place in the past and an investigation into QMUL's data handling practices may be warranted.

There have been a few cases of NHS organisations being fined for data security breaches. [17] Different to the circumstances relating to this FOIA request, the breaches in those cases generally involved inadequate security practices or administrative errors rather than faulty anonymisation, e.g. inadvertent disclosure of medical records with identifying details attached. There have also been concerns over anonymisation of NHS databases, but that involves far more data variables including many direct and indirect personal identifiers, unlike this FOIA request which contains none.

2.6) Alternative explanations for participants' alleged concerns with confidentiality

The PACE trial consent form allows withdrawal of consent without explanation. QMUL asserts that two participants withdrew consent because they were concerned that QMUL could not keep their confidential (identifiable) information private. One case is loosely attributed to a FOIA request.

16. http://www.virology.ws/2016/01/19/at-least-were-not-vexatious/
17. http://www.buildingbetterhealthcare.co.uk/technical/article_page/Comment_Medical_records_for_sale/95496

However, there are alternative explanations for participants' concerns with confidentiality.

a) In February 2010, Professor Malcolm Hooper (Emeritus Professor of Medicinal Chemistry, University of Sunderland) released a document on the internet that was highly critical of the PACE trial and included claims of data security breaches that may concern trial participants: [18]

i) Page 255 asserts that *"It was in 2005 (ie. during the life of the PACE trial) that one of the PACE Trial Principal Investigators, Professor Michael Sharpe, inadvertently leaked a computer file containing a confidential list of over 70 patients' names and addresses which he sent to a member of the public, who unknowingly forwarded the information to other people."* Awareness of this claim may have concerned some patients about confidentiality in the PACE trial.

ii) Page 256 (based on a previous FOIA request [19]) reveals that in March 2006, lax data security practices at King's College London allowed the theft of a digital audio recorder. The device contained recordings of six sessions of GET in the PACE trial. It is possible that details about the theft were included in the information from the Strategic Health Authority. It is curious Professor Peter White stated that the recordings of individual patients' therapy sessions *"are not believed to contain any sensitive personal information"*, as: *"The therapist has confirmed that in accordance with the trial SOP, she never uses any identifiable information in any recordings. PIN and the date of session are the only data recorded regarding personal identification. This therapist does not use initials of the participant in the recording."* Yet QMUL are now arguing that summarised and de-identified scores from questionnaires for fatigue and physical function (etc) are highly confidential and must not be released to the public under any circumstances.

The stolen device should not pose any problem for my FOIA request, as it is unlikely that the recordings could be cross-linked with the disputed information to re-identify participants. Additionally, to my knowledge, no trace of the recordings has ever been made available. There is also no indication whatsoever that the theft was in any way motivated by the PACE trial, and was most likely an opportunistic act, as the device was left unsecured.

b) In a series of articles published on the popular Virology Blog, David Tuller (Lecturer in Public Health and Journalism, University of California, Berkeley) covered the PACE trial and explored how the investigators violated the Declaration of Helsinki, by failing to declare their conflicts of interest to participants until after the trial was over. [20] As a result, *"Some PACE trial participants were unpleasantly surprised to learn only after the trial of the researchers' financial and consulting ties to insurance companies."* Tuller interviewed four trial participants. Two said they would have agreed to be in the trial anyway because they lacked other options. One may not have participated if she knew, as she was skeptical of ties to the insurance industry. One withdrew consent retroactively and forbade the researchers from using her data, and stated: *"'I wasn't given the option of being informed, quite honestly,' she said, requesting anonymity because of ongoing legal matters related to her illness. 'I felt quite pissed off and betrayed. I felt like they lied by omission.'"* Tuller stated about participants: *"They felt this violated their rights as participants to informed consent. One demanded her data be removed from the study after the fact."* [21]

Similarly, Professor Malcolm Hooper's complaint to the Lancet (on the PACE trial) contains

18. http://www.meactionuk.org.uk/magical-medicine.pdf ("Magical Medicine; How To Make A Disease Disappear.")
19. https://dl.dropboxusercontent.com/u/23608059/PDW-re-theft.pdf
20. http://www.virology.ws/2015/10/22/trial-by-error-ii/
21. http://www.virology.ws/2016/01/04/trial-by-error-continued-questions-for-dr-white-and-his-pace-colleagues/

disturbing accounts of events from several trial participants. [22] Of particular note, one participant (a professional with a background in mental health) assigned to CBT, describes how his therapist's *"prime concern was to obtain the desired results in keeping with preconceived views"*; the participant also reports that when trying to disengage from the trial, the therapist's *"behaviour was totally unethical and unprofessional"*; this participant became very concerned when discovering later that the therapist in question was a provider for insurance companies: *"This is surely of immense significance in relation to the PACE Trial, as how could (he) have been objective in his role as research therapist when he is a provider to insurance companies."*

Moreover, based on a possible interpretation of the wording used in the consent form [23], one of the organisations which potentially had "audit" access to patients' personal data was the UK Department for Work and Pensions (DWP). Patients involved in disputes with the DWP may become concerned over being falsely declared "fit for work". The trial participants were also asked multiple questions about welfare benefits and insurance payments, which may have caused some participants additional concern, more so if they later discovered elsewhere that PACE investigators failed to disclose their COIs with the insurance industry during the recruitment process.

While many things may have concerned PACE trial participants about confidentiality, I propose that it is the information about the conduct of the trial that is more likely to have concerned participants, rather than the belief that the FOIA had led to the release of personal data.

2.7) Experiences of trial participants and their alleged views about disclosure

QMUL announced their intention to seek advice from patients about data sharing [24], and (according to a case note), Professor Peter White intends to discuss at the hearing, *"the experiences of any trial participants who have been identified, and participants' views about disclosure"*. In their Grounds of Appeal, QMUL asserts: *"Participants would be distressed by the fear that information about themselves and their health would be made public as a result of the disclosure. They would also be distressed by the fear that their participation in the PACE trial would be made public as a result of the disclosure, and that as a result they would be exposed to criticism or harassment from opponents of the trial."* However:

a) No participant or patient has "been identified" and such wording is potentially misleading. No evidence has been presented that anyone has attempted to identify participants, and no plausible mechanism has been demonstrated to show how participants might be identified in the future.

b) Participants who came forward to discuss and share their experiences on the internet were shown appreciation and sympathy by other patients, without signs of criticism or harassment. A document has been prepared which aimed to collect <u>all</u> publicly available accounts of participants. [25] Sixteen accounts were found, in various locations, and made over several years. The majority, though not all, are highly critical of the PACE trial e.g. due to being mislead about success rates, negative experiences of the interventions, or being poorly treated by research staff when raising concerns about adverse effects. There is no evidence of any criticism or harassment of participants who came forward, regardless of the content of their report. There is evidence of the opposite (many online comments from fellow patients express gratitude for the participants having taken part in research and offer support for their shared health problems). The Tribunal may be interested in

22. http://www.meactionuk.org.uk/COMPLAINT-to-Lancet-re-PACE.doc (p39-41)
23. https://www.whatdotheyknow.com/request/203455/response/508208/attach/3/Consent%20forms.pdf
24. http://www.qmul.ac.uk/media/news/items/smd/168729.html
25. https://sites.google.com/site/pacefoir/pace-trial-participants-experiences.pdf?attredirects=0&d=1

reviewing these anecdotal accounts and comparing them to those presented by QMUL.

c) Participants who fear disclosure may have been influenced by misinformation. QMUL exaggerates the likelihood of re-identification, and promotes the view that participants are likely to be exposed to criticism and harassment for their participation. Thus, QMUL may have unnecessarily distressed trial participants and biased their views against disclosure, despite the risk of re-identification being remote. Discussions about the alleged consequences of disclosure are largely irrelevant, as personal identifiable data was not requested.

d) QMUL should disclose to the Tribunal all details on how the private views of participants and any other patients or advocates were acquired: **i)** How were individuals whose views were sought, identified and recruited? **ii)** What were they told about the request and the risks of disclosure? **iii)** Were they made fully aware of the strong public interest in disclosure and that the ICO rejected QMUL's arguments and ordered disclosure? **iv)** Was anybody not invited to contribute, and if so, how was selection made? **v)** What effort was made to include dissenting or critical voices?

e) Patients can often be much more critical of the treatment they receive when talking freely amongst themselves than when talking with medical staff in positions of authority.

f) As the lead investigator of this controversial trial (who is against disclosure), Dr. White is presumably representing the interests of QMUL, PACE, and himself. These interests are not necessarily the same as those of patients in general or the public interest in disclosure.

g) With reference to seeking other patients' views, the ME Association has written to QMUL urging them to comply with the Information Commissioner's decision, as *"all the feedback we are receiving indicates that people with ME/CFS want to see this data released"*. [26]

2.8) FINE trial investigators have published similar individual patient data

Again, the respected and popular PLOS journal publisher now requires publication of all data underlying a summary article, including individual patient data. The disputed information passes the revised data sharing policy used to publish individual patient data from the FINE trial. [27] FINE was the 'sister' trial to PACE and both were funded by the Medical Research Council (MRC). The timing, design, patients, outcomes, and interventions, were all similar.

The disputed information contains 12 linked variables and no participant ID numbers, whereas the dataset released by FINE contains 18 linked variables including participant ID numbers. Both contain the same type of information about fatigue scores, physical function scores, whether they met a diagnostic criteria for the condition, and which specific group they were randomised to. Upon release of the dataset, PLOS issued this statement: *"The authors have prepared a dataset that fulfills requirements in terms of anonymity and confidentiality of trial participants, and which contains only those variables which are relevant to the present study."*

The above clearly contrasts to the approach of QMUL. By conducting a similar study to PACE and publishing in PLOS One with a liberal data sharing policy, Goldsmith et al.'s publication seriously undermines the assertions by QMUL that granting my FOIA request is a violation of anonymity, confidentiality, MRC data sharing guidelines, etc. QMUL's far-fetched concerns have not prevented the FINE group from voluntarily providing open public access to individual patient data (FINE

26. http://www.meassociation.org.uk/2016/02/me-association-writes-in-support-of-foi-request-relating-to-release-of-pace-trial-data-9-february-2016/
27. http://journals.plos.org/plosone/article?id=10.1371/journal.pone.0144623

clearly do not believe that participants will be identified). It is difficult to see how the disputed information is a violation of patient privacy given the above. No FINE trial participant has, or unlikely ever will be identified from the individual patient data published.

2.9) Consideration of Principle 1 of the DPA (if at all relevant)

The ICO decision notice FS50565190 concludes that the disputed information does not constitute personal data, will not lead to re-identification, and therefore it is not protected by the DPA. QMUL maintains that disclosure of the disputed information would breach Principle 1 of the DPA: "*Personal data shall be processed fairly and lawfully and, in particular, shall not be processed unless – (a) at least one of the conditions in Schedule 2 is met, and (b) in the case of sensitive personal data, at least one of the conditions in Schedule 3 is also met.*"

Fairness in the DPA is primarily based on factors such as: considering whether disclosure would have significant consequences i.e. cause unjustified damage or distress to data subjects; considering the data subjects' reasonable expectations of what would happen to their personal data; considering the balance of whether the legitimate interests of the public are sufficient to justify any negative impact to the rights and freedoms of the individuals involved.

a) QMUL argued to me that the disputed information "effectively" consists of sensitive personal data, and that disclosure would cause unjustified damage or distress to the trial participants. However, their assertions are fundamentally based on a hyperbolised estimate of risk, and such exaggeration may itself generate distress in participants, despite the risks being insignificant. Misleading headlines prompted by published papers from QMUL/PACE and poorly-worded press releases/conferences have already caused patients more distress than will ever be caused by releasing the disputed information to the public (see Part 6). As one PACE trial participant recently stated: *"the press coverage was dreadful and extremely misleading."* [28]

b) PACE trial participants would reasonably expect that they are not identified by the public, as promised in the consent form. QMUL has argued that confidentiality agreements with participants would not allow the disclosure of sensitive personal information from the trial, and that disclosure of such information is likely to be unfair. Again, the disputed information is not sensitive personal data, and QMUL base their assertions on a hyperbolised estimate of risk. Based on confidentiality guidelines (from the NHS, GMC, ICO, and others), de-identified data is not confidential, as it will not identify individuals, and consent is not needed to anonymise their data. The trial consent forms do not explicitly rule out disclosure of anonymised data, there will be no significant or actionable breach of confidentiality, and the main promise to trial participants that they will not be identified will be kept, as anonymity will be preserved (see Part 3). §37 of the Information Commissioner's Response explains why it is "remarkable" to expect the duty of confidence to cover all data regardless whether it is likely to identify anyone. If any participants express concern, see Part 2.7 "Participants who fear disclosure may have been influenced by misinformation".

Assuming that participants' expectations are relevant to the release of sufficiently anonymised data from a publicly funded trial that impacts on the lives of other patients; they probably expected that the principal investigators would publish the results as promised in the published trial protocol before the trial was completed, as did BMC Neurology when it published the protocol. This was not done for the primary outcomes or the recovery criteria. It is doubtful that participants would have

28. https://www.actionforme.org.uk/forum/thread/22/debunking-pace-trial#dis-post-172

expected such extensive, major, post-hoc, and possibly unapproved deviations from the protocol after the trial was over, some of which were not only demonstrably flawed but led to the data being used to support misleading statements from the PACE trial investigators, and then further distorted and widely disseminated by the press. The revised “recovery” criteria substantially underestimates the severity of patients' illness and disability: e.g. the thresholds for normal fatigue and physical function overlap with trial entry criteria for severe and disabling fatigue, with none of the recovery criteria, individually or combined, representing a full “recovery”. All this leads to unrealistic expectations of patients to recover with treatment, to their obvious detriment (see Part 6).

With respect to balancing the interests of data subjects and the interests of the public (e.g. others who want a re-analysis of trial data), QMUL argues that much information about the trial and the results is already freely available. This however fails to take into account the insufficiencies and problems with that information, or the public interest in disclosing the disputed information.

c) QMUL's arguments for the public interest in withholding the disputed information are, again, fundamentally based on a substantially exaggerated estimate of the risk of re-identification. There will be no significantly negative impact on the rights and freedoms of the data subjects, as there is no significant risk of re-identification, and the public interest in disclosure is strong and overrides any minor doubts about anonymisation if they exist.

It is important that the public has access to accurate, stringent, and verifiable assessments of results. QMUL/PACE failed their responsibility to provide complete, accurate, and meaningful reports on recovery from ME/CFS, as expected in the Declaration of Helsinki (etc). Previous reports were undermined by demonstrable flaws, highly contentious or poorly justified changes to endpoints, and uncorrected factual errors. ME/CFS is widely regarded as disabling and difficult to treat, and once established, a full recovery or return to premorbid health is rare. Claims of improvement or recovery should be based on stringent standards and thoroughly tested. Concerns about the analysis of the PACE trial results have been expressed by academics, researchers, scientists, journalists, and numerous patients and advocates with various backgrounds or qualifications. [29,30] Over 11,000 individuals signed an independent petition calling for something to be done about it i.e. the retraction of misleading claims and the re-analysis of trial data. [31] QMUL has consistently failed to sufficiently acknowledge or address the multiple problems identified. [32,33]

The disputed information will address longstanding confusion and correct misleading statements. The public interest favours independent, open / transparent (publicly verifiable) re-analysis of data. Qualified researchers have expressed interest in analysing this data for a peer reviewed publication. There is no absolute guarantee that data cannot be misinterpreted when publicly disclosed, but this does not provide a legal ground for withholding information. [34] Errors and misrepresentations of the trial data have already occurred under the direction of QMUL and the PACE group, but unlike the current situation, public disclosure allows rapid verification, scrutiny, and correction of errors with any new analysis of the results. It is unlikely that any rogue analysis would be given much weight or survive scrutiny if it is not part of a properly peer reviewed publication.

While as a patient myself I take patient confidentiality seriously, the necessity of openly resolving

29. http://www.virology.ws/mecfs/ (list of articles by journalist David Tuller DrPH on ME/CFS and PACE at Virology Blog)
30. http://news.sciencemag.org/health/2015/10/criticism-mounts-long-controversial-chronic-fatigue-study
31. http://my.meaction.net/petitions/pace-trial-needs-review-now
32. http://www.virology.ws/2016/01/04/trial-by-error-continued-questions-for-dr-white-and-his-pace-colleagues/
33. http://www.virology.ws/2015/10/30/david-tuller-responds-to-the-pace-investigators/
34. http://www.ijdc.net/index.php/ijdc/article/download/204/273

the PACE trial controversy extends beyond any individual. The unresolved PACE trial controversy potentially affects millions of patients around the world and must be promptly resolved. The balance of the public interest outweighs the individual interests of QMUL and myself. The multiple benefits in disclosing the disputed information clearly outweigh the minimal risk.

2.10) Consideration of conditions for processing (Schedules 2 and 3 of the DPA)

As the disputed information is sufficiently anonymised or de-identified, the DPA is inapplicable. However, I will briefly consider the conditions for processing if applicable:

With respect to conditions for fair processing in Schedule 2 of the DPA i.e. processing of personal data, these mostly relate to whether processing is necessary to achieve legitimate interests. I will defer to the Tribunal as to whether any conditions are met here when considering the public interest and the purpose or importance of this request as described elsewhere in this response e.g. Part 6.

With respect to conditions for fair processing in Schedule 3 of the DPA i.e. processing of sensitive personal data, I will defer to the Tribunal as to whether any conditions are met, given the purpose and importance of this request as described elsewhere in this response e.g. Part 6. I ask the Tribunal to consider these conditions: *"publication in the public interest"*, *"for research"*.

2.11) De-identification or anonymisation is not prohibited processing

Principle 2 of the DPA does not allow data controllers to process personal data for further "incompatible" purposes. However, this FOIA request does not involve releasing sensitive or personal data to the public, so it does not contravene this principle. Nevertheless, the question may arise whether anonymisation is itself a form of processing, and whether the data controller is allowed to process sensitive personal data for the purposes of anonymisation. According to multiple references such as the ICO guideline titled 'Anonymisation: managing data protection risk code of practice', the DPA should not prevent the anonymisation of personal data for FOIA requests, and anonymisation allows the use of data in *"new and different ways because the DPA's purpose-limitation rules do not apply to it"*. Similarly, the ICO's specialist guide on 'Personal information (section 40 and regulation 13)' states that: *"We consider that a FOIA disclosure that complies with the DPA in other respects will not breach the second principle."*

Whether anonymisation e.g. by redaction is itself a form of processing, was central in a Tribunal decision; All Party Parliamentary Group on Extraordinary Rendition v The Information Commissioner & The Ministry of Defence [2011]. It was concluded that disclosing anonymised information which cannot identify individuals is not "processing" personal data under the DPA.

2.12) The wider research community is heading towards open data

Public disclosure of individual patient data, while protecting privacy, is becoming more common. The wider research community is heading towards increased transparency and open data in clinical trial research (often including individual patient data). This issue will be covered in Part 6.

Part 3: Response to exemption S.41 [confidentiality agreements]

This is a response to QMUL's Second Ground of Appeal: Section 41.

Many of the counter-arguments against S.40(2) described in Part 2 are also highly relevant to S.41. The below subsections focus on the aspects of confidentiality and consent.

3.1) S.41 only applies if there is an 'actionable' breach of confidence

According to the Ministry of Justice guidance on S.41, the exemption only applies if disclosure would allow data subjects to bring successful legal action against the public authority. [35]

Similarly, JISC's 'Freedom of Information and Research Data Q&A' states: *"Simply stating that information is confidential is not enough; there must be a real likelihood that disclosure would open the public authority to legal action for breach of confidence."* [36]

The Universities UK website hosts a document prepared to assist them in formulating their approach on the treatment of unpublished research data under current freedom of information legislation. It states that S.41 *"is of doubtful application to (eg) medical data confidentially obtained from research subjects which have been anonymised"*. [37]

In the (unrelated) ICO decision notice FS50424953, the Commissioner noted: *"a confidentiality clause in a contract is not enough in itself to prevent disclosure. If it were it would be relatively straight forward for all public authorities bound by the FOIA to opt out of their obligations under the FOIA."* In that case, the Commissioner accepted that there was an obligation of confidence, but decided that the S.41 exemption was not engaged, as there was no actionable breach of confidence. The case went to a Tribunal (EA/2012/0114), who decided that save for the redaction of three names which were exempt under S.40, the disputed information should be disclosed.

Similarly, the guideline hosted on the NHS Health Research Authority's website, titled 'Information Sheets & Consent Forms. Guidance for Researchers and Reviewers. Version 3.6.1 March 2011', outlines the legal position within the UK: [38] The DPA allows medical data to be used for any medical research purpose without the need for the consent of individuals, and that it is a common misconception that the DPA always requires consent from subjects to process their data, when in fact in most cases the act will almost never require consent for the processing of data for research. Although this guideline is not necessarily referring to the FOIA, it demonstrates another scenario where patient data is routinely shared without their explicit consent.

It is highly unlikely the disputed information will cause substantial harm to PACE trial participants e.g. serious invasion of their privacy, as described in the definition of a breach of confidence. It is therefore highly doubtful that participants could bring successful legal action against QMUL if they will not be identified (nor suffer the alleged consequences), and therefore granting this FOIA request does not constitute an actionable breach of confidence.

3.2) Confidentiality guidelines are concerned with identifiable information

The essential principle of confidentiality guidelines is that the identity of data subjects must not be revealed without consent, not that any data whatsoever cannot be released without consent:

In the UK Department of Health's 'Confidentiality: NHS Code of Practice' (2003), definitions are given and distinctions are made between identifiable information, anonymised information, and pseudonymised information: *"Patient identifiable information: Patient's name, address, full*

35. http://www.justice.gov.uk/downloads/information-access-rights/foi/foi-exemption-s41.pdf
36. http://www.jisc.ac.uk/media/documents/publications/programme/2010/foiresearchdata.pdf
37. http://www.universitiesuk.ac.uk/highereducation/Documents/2013/IPBillBriefingAnnex1.pdf
38. http://www.hra.nhs.uk/documents/2013/09/information-sheet-and-consent-form-guidance.pdf

postcode, date of birth; Pictures, photographs, videos, audiotapes, or other images of patients; NHS number and local identifiable codes for patients; Anything else that may be used to identify a patient directly or indirectly." [39] According to the code, the confidentiality and sensitivity of medical information is fundamentally determined by whether it can identify individual patients. Furthermore, "*anonymised information is not confidential and may be used with relatively few constraints [...] once information is effectively anonymised it is no longer confidential*".

The GMC's 'Confidentiality guidance: Protecting information' is primarily concerned with *"identifiable information about patients"*, but this FOIA request does not involve identifiable information about patients (who were involved in a publicly-funded clinical trial). [40] The GMC's 'Confidentiality guidance: Research and other secondary uses' states that *"for many secondary uses, it will be sufficient and practicable to disclose only anonymised or coded information"*, which included research that *"can serve important public interests"* [41]

3.3) De-identified data is not confidential and does not require consent

As per guidelines from the ICO, GMC, and NHS, sufficiently anonymised or de-identified data is not confidential and consent is generally not needed to legitimise an anonymisation process. In most jurisdictions, including the European Union, anonymisation is permitted without consent. [42] Two expert commentaries indicate that in the UK, anonymisation of confidential data can replace the for consent, that this alteration preserves confidentiality, and that it should change the nature of the data so that in most contexts it is no longer classified as 'personal data' and thus not subject to the legal duties of data protection: 'How safe is releasing anonymised confidential data?' (apira.co.uk) [43] and 'Records, Computers and Electronic Health Record' (patient.co.uk). [44]

3.4) Ambiguities with QMUL's claims about data sharing

QMUL asserted that confidentiality agreements prevent disclosure of the disputed information. §36-37 of FS50565190 suggests QMUL argued to the ICO that due to the promise of confidentiality, *"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"*. In previous correspondence with me, QMUL also asserted that the "sensitive personal data" was consented *"for a specific limited purpose only i.e. for disclosure only to individuals associated directly with the PACE Trial, for its research analysis in this trial"*. [45] Yet PACE investigators published a paper in PLOS One which in 2012 expected routine data sharing among any researcher upon reasonable request [46] and selectively shared "anonymised" individual patient data (IPD) with researchers outside the PACE group. [47]

The consent form [48] and patient invitation newsletter [49] are both somewhat ambiguous about who can access patient data, but they do not explicitly rule out the sharing of anonymised or de-identified IPD, and arguably the most important promise and purpose is that the identities of participants will be protected. There is room for interpretation over exactly what information is

39. https://www.gov.uk/government/publications/confidentiality-nhs-code-of-practice
40. http://www.gmc-uk.org/guidance/ethical_guidance/confidentiality_12_16_protecting_information.asp
41. http://www.gmc-uk.org/guidance/ethical_guidance/confidentiality_40_50_research_and_secondary_issues.asp
42. http://www.bmj.com/content/350/bmj.h1139
43. http://www.apira.co.uk/userfiles/files/ClinRiskArtPart1.pdf
44. http://www.patient.co.uk/doctor/records-computers-and-electronic-health-record
45. https://www.whatdotheyknow.com/request/selected_data_on_pace_trial_part
46. http://journals.plos.org/plosone/s/data-availability
47. http://www.qmul.ac.uk/media/news/items/smd/168729.html
48. https://www.whatdotheyknow.com/request/203455/response/508208/attach/3/Consent%20forms.pdf
49. http://www.wolfson.qmul.ac.uk/current-projects/pace-trial#trial-information

expected to remain undisclosed, but the agreement for the protection and sharing of personal data would primarily cover identifiable medical information.

While the consent form itself does not explicitly give permission for other researchers (there is only mention of "responsible individuals" from "regulatory authorities"), the information sheet given to patients when invited to participate is referred to in the consent form and states that: *"And occasionally, other researchers will need to see your notes so they can audit the quality of our work. An audit might be run by one of the universities helping with our study or hospital regulatory authorities, or by one of the organisations funding our study."*

While many more data variables than I have requested were shared with other researchers under ad hoc confidentiality agreements, this demonstrates that releasing anonymised IPD is not prohibited. The disputed data does not, as QMUL has previously claimed to me, "contain medical information that might identify the patient". Again, their claim that the disputed information is confidential, is fundamentally based on their substantially exaggerated assessment of the risk re-identification.

The FOIA and DPA were in effect before the PACE trial started, and research datasets from public authorities were always subject to this legislation. It was and is QMUL's responsibility to be aware of the legislation and comply with it. QMUL should have been aware that they might have to release such data in accordance to the FOIA and DPA, and therefore should have accounted for the reasonable possibility of disclosure of some trial data under the FOIA legislation. The trial was also designed to protect the identities of patients from PACE researchers. Disclosure of the disputed information would not breach the promise to participants that they will not be identified.

3.5) FINE trial published individual patient data without violating confidentiality

The details of this and the relevance to the PACE trial is covered in Part 2.8 "FINE trial investigators have published similar individual patient data". The conclusion is that individual patient data can be published while maintaining confidentiality and anonymity.

3.6) The public interest in disclosure can override remaining doubts

Confidentiality guidelines typically allow consideration of the public interest in disclosure. I am not arguing that a serious violation of identifiable personal information is warranted, but I believe that the public interest in disclosure overrides any minor remaining doubts about confidentiality (Part 6).

Part 4: Response to exemption S.43(2) [commercial interests]

This is a response to QMUL's Third Ground of Appeal: Section 43(2).

S.43(2) is a prejudice based exemption and is also subject to a public interest test. The guidance on S.43(2) in relation to research datasets and the FOIA is very generalised. Therefore, I relied on the guidance provided by the Ministry of Justice and the ICO, with occasional reference to other resources which cover these issues in relation to research and universities.

4.1) QMUL's arguments are based on inaccurate risk assessments

In ICO decision notice FS50565190 and QMUL's Grounds of Appeal, it was argued that disclosure of the disputed information would be likely to prejudice QMUL's commercial interests because it

may affect its ability to conduct research and attract funding. It was similarly argued that disclosure would damage their reputation and affect their ability to attract staff and students.

To support their arguments, QMUL asserted that disclosure would encourage existing PACE trial participants to withdraw permission for the continued use of their data, would deter those participants from taking part in any long term follow-up, and would deter other individuals from agreeing to take part in similar research in the future. QMUL also believes that the public interest in withholding the disputed information outweighs the public interest in disclosing it.

Again, QMUL's arguments for applying the S.43(2) exemption are fundamentally based on inaccurate assessments that substantially exaggerate the risk of re-identification. I asked for the bare minimum of data required for the intended analyses, and QMUL has provided no convincing evidence that there is a significant risk (see Part 2 and Part 3). The ICO rejected QMUL's arguments because of the lack of evidence, despite repeatedly requesting it.

QMUL provided *"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"*. The wording suggests that the timing of events may have been coincidental. There is no convincing evidence that the disputed information can be cross-linked with any other FOIA requests. The ICO concluded that even if only one single participant (out of 641) may have been discouraged from future participation due to the FOIA, this would not present a significant problem for QMUL.

There is serious doubt about the alleged damage to future research and funding prospects. Furthermore, it is more likely that QMUL and PACE are damaging their own reputations by failing to sufficiently acknowledge or address the multiple problems that prompted this FOIA request. Non-disclosure may cause more damage than disclosure (see Part 6). S.43(2) does not protect against non-commercial reputational interests, such as the results of any re-analysis. See Part 5 for more information about issues relating to the research programme, and why the data collection for the research programme was already completed before submitting the FOIA request.

4.2) The public interest in disclosure can override commercial interests

The strong public interest in disclosure is covered elsewhere (Part 2.9b-c, Part 5, Part 6). However, there are some specific issues which are more relevant to exemption S.43(2) of the FOIA:

In a meeting between the ICO and representatives of the higher education sector (September 2010), which discussed the implications of the FOIA in relation to research programmes: *"The ICO made clear that its job is to administer the law as it exists and to ensure that 'public authorities', including universities, adhere to the letter and spirit of the law. [...] In so doing, it also recognises that universities operate in a competitive environment different from that of other organisations subject to the FOI Act and the EIR; but that environment does not of itself warrant exemption from the release of information. From the universities' side there are growing moves, alongside the Research Councils, to implement open access and open data initiatives."* [50]

Open data initiatives would not be growing if they were too damaging to commercial interests. Organisations and individuals who have rejected commercial interests as an excuse to ignore patients' concerns, selectively withhold trial results, or tightly restrict trial data, include: the

50. http://www.rin.ac.uk/system/files/attachments/FOI_article_for_CILIP_Jan_2011.doc

European Medicines Agency [51], the Cochrane Collaboration [52], Peter Gøtzsche (co-founder of the Cochrane Collaboration) [53], and Fiona Godlee (editor in chief of the BMJ) [54].

In 2013, the British Medical Journal called for a "patient revolution" (of engagement), as *"The preservation of institutional bureaucracies, as well as professional and commercial vested interests, have consistently trumped the interests of patients."* [55] In 2011, a UK House of Commons select committee published an extensive report into peer review in scientific publications; while the report acknowledged that commercial interests may be relevant in certain circumstances, it also states that *"unless there is a strong reason otherwise, everything should be out there and available"*. [56]

Part 5: Response to exemption S.22A [detriment to research]

This is a response to QMUL's Fourth and Fifth Grounds of Appeal: Section 22A.

5.1) Section 22A is not applied retrospectively to previous FOIA requests

In FS50565190, QMUL explained that follow-up in the PACE trial "continued until mid-2012", but "analysis of the data continues to this day and papers continue to be published". However, this FOIA request was submitted and responded to before S.22A came into effect on 1 October 2014. There is no convincing reason why S.22A should be applied retrospectively to this FOIA request, but I have pre-empted the limited possibility that the Tribunal may consider it.

As S.22A is a qualified exemption, the case of prejudice against the interests of the public authority must be convincingly argued and then balanced or compared with the public interests. QMUL argued that even if they were in breach of the FOIA, the ICO had the discretion to not require QMUL to disclose the requested data due to "exceptional circumstances". I agree with the ICO that there are no exceptional circumstances here, and I believe that S.22A would not prevent disclosure even if applied, as the strong public interest in disclosure would prevail.

5.2) QMUL has already published repeatedly using the disputed information

While S.22A includes research programmes that have a view for future publication, the fact that the main part of the PACE trial is over diminishes the reasons for non-disclosure.

According to the Research Councils UK Common Principles on Data Policy, it is fair that creators of research data have a right to reasonable first use within a limited period of time. [57]

The disputed information is based on a 52 week follow-up assessment of participants, which was completed over 6 years ago in January 2010 (or about 4 years at the time of the request). Multiple papers using this data have been published: e.g. February 2011 (PMID:24225069), August 2012 (PMID:22870204), January 2013 (PMID:23363640), April 2014 (PMID:24913337), and others. QMUL/PACE have already published their main analyses of this data and have since moved on to other aspects of the research programme, such as analysing a wide range of outcome measures not being requested, and for longer follow-up periods e.g. 2.5 years (PMID:26521770). They have still

51. http://blogs.nature.com/news/2014/10/europes-milestone-medical-data-transparency-rules-finally-confirmed.html
52. http://community.cochrane.org/organisational-policy-manual/27-access-data-all-trials
53. http://www.cochranelibrary.com/editorial/10.1002/14651858.ED000035
54. http://www.alltrials.net/news/who-calls-for-all-clinical-trial-results-to-be-published
55. http://www.bmj.com/content/346/bmj.f2614.long
56. http://www.publications.parliament.uk/pa/cm201012/cmselect/cmsctech/856/85602.htm
57. http://www.rcuk.ac.uk/research/datapolicy

not published the primary outcomes and recovery estimates as pre-specified in the trial protocol published in March 2007, or any other type of analysis suggested in my correspondence.

If the essential intention of research exemptions in the FOIA (S.22 and S.22A) is to protect information pertaining to research from premature disclosure, this FOIA request does not impinge on the right to publish first with this data, or to publish additional papers using other types of outcomes or follow-up periods not covered by this request. I only requested a very small proportion of numerous outcome measures and other follow-up periods studied in the trial.

5.3) Five year follow-up should be collected and is not the same programme

In previous correspondence with me, QMUL asserted that releasing the disputed information would interfere with the 5 year follow-up because it could (allegedly) identify patients and deter them from further participation in follow-up studies. However, the risk of re-identification is remote, and I had doubted QMUL's claims about 5 year follow-up, because such data should have already been collected several months before I submitted this FOIA request or 20 working days after the request was received (and surely collected by now, approximately 2 years later). The 2.5 year follow-up assessment was completed in April 2011 (PMID:26521770).

QMUL's Grounds of Appeal provides a minor clarification on this issue (emphasis added): *"At the time of the FOIA request giving rise to the present appeal (described below), an application was underway for funding for a long-term (five years and more) follow-up trial of the participants in the PACE trial. Funding for a feasibility study to do this follow up study has now been agreed and this study will start shortly, once research governance approvals have been obtained."*

However, the 5+ year follow-up period was not part of the original research programme, and applying for funding is not the same as receiving funding and approval. When the request was submitted in March 2014, there was no guarantee that the application would be approved, and PACE already had the data for the original research programme. Furthermore, the 5+ year follow-up data is much less important or reliable than 52 week / 1 year follow-up, as explained below.

5.4) Longer follow-up data is less important due to treatment 'contamination'

In previous correspondence with me, QMUL asserted that analysing the 2.5 year follow-up data has made the case to examine 5 year follow-up data, and that *"This is important so that patients and their healthcare professionals can learn whether improvements are maintained or enhanced a long time after treatment, or whether such patients relapse after stopping treatment."*

The main results from the 2.5 year follow-up were published in October 2015 (PMID:26521770). As this demonstrated no significant differences between groups, this means that none of the adjunctive therapies tested in the PACE trial have any long-term effect. Those in the original SMC, APT, and CBT groups, showed significant improvement without additional therapy. The majority of those in the original SMC and APT groups received no additional treatment but (on average) still caught up with the other groups originally assigned to either CBT or GET. The original GET group made no further significant improvement regardless of further treatment. The sub-group analyses also indicated that receiving additional CBT or GET after the 1 year follow-up was not associated with improvement in any group (i.e. they were not significantly effective).

The trial design also encouraged participants to try different interventions after the main 1 year follow-up period, thereby destroying the randomisation in the trial and thus introducing serious

biases which are very difficult to correct in analysis. James Coyne [58] (Professor Emeritus of Psychology, University of Pennsylvania; Professor of Health Psychology, University Medical Center, Groningen) and Keith Laws [59,60] (Professor of Neuropsychology, University of Hertfordshire) have both written articles describing this problem. Coyne and Laws co-authored a letter published online in Lancet Psychiatry [61] that reiterated how the "unregulated crossover between treatments during follow-up" made the follow-up data "uninterpretable", and that *"the lack of between-group differences at follow-up takes precedence over within-group differences […] evidence in the long-term follow-up is unconvincing"*. Loss to follow-up was 25%, and PACE confirmed that the follow-up study was not *"a continuation of the trial (with or without crossover), but rather a naturalistic follow-up after trial completion"*. [62] (emphasis added)

It is therefore unlikely that the 5+ year follow-up assessments will be significantly different, or produce any data that is reliable enough. It is more important that the 1 year follow-up data is evaluated further to establish more useful estimates of the temporary benefits.

5.5) Disclosure of the disputed information itself will not be detrimental

The prejudice test must determine the nature, strength, and likeliness of prejudice. Guidance on S.22A was very limited until recently when the ICO updated their guidance on parent S.22.

In QMUL's Grounds of Appeal, it was argued that the prejudice would arise because disclosure would (allegedly) induce some participants to withdraw from the trial or withhold consent for the continued use of their existing data. It was also argued that there is an overriding public interest in avoiding prejudice to a research programme of this nature. QMUL's arguments are fundamentally based on inaccurate assessments that exaggerate the risk of re-identification (see Part 2 and Part 3). QMUL may be contributing to any fear of disclosure by substantially exaggerating the risks and by promoting the view that participants are likely to be exposed to criticism and harassment.

In the relevant ICO decision notice (FS50565190), in relation to S.43(2), the Commissioner concluded that there was insufficient evidence that disclosure would likely lead to a significant number of current participants withdrawing from the trial. QMUL presented evidence that two participants withdrew from the trial due to concerns about confidentiality, one which coincidently occurred after the release of information under the FOIA. However, the ICO seemed to view this as evidence that there would be no exodus of participants if QMUL disclosed the disputed information. I have already responded to these issues in Part 2 on S.40(2), Part 3 on S.41, and Part 4 on S.43(2). Non-disclosure may cause more damage than disclosure (see following subsections).

5.6) Importance of freedom of information to research from universities

QMUL argues that disclosure of the disputed information could have wider ramifications. However, after growing awareness of questionable publication practices in general, there are also mainstream efforts to increase public scrutiny by making trial data more widely available. Part 6 will cover the trend of increased transparency and enforcement of open data in the research community. The FOIA is a legitimate mechanism for ensuring that QMUL shares trial data fairly without favouritism.

58. http://blogs.plos.org/mindthebrain/2015/10/29/uninterpretable-fatal-flaws-in-pace-chronic-fatigue-syndrome-follow-up-study
59. http://keithsneuroblog.blogspot.co.uk/2015/11/pace-thoughts-about-holes.html
60. http://keithsneuroblog.blogspot.co.uk/2015/11/song-for-siren.html
61. http://www.thelancet.com/journals/lanpsy/article/PIIS2215-0366(15)00551-9/fulltext
62. http://www.thelancet.com/journals/lanpsy/article/PIIS2215-0366(16)00018-3/fulltext

Research datasets have always been subject to the FOIA (March 2005) [63], and researchers sometimes use the FOIA to access information that is otherwise not disclosed. [64,65] S.22A broadens the S.22 exemption but does not diminish the importance of freedom of information.

Richard Thomas (Information Commissioner from 2002-2009) stated: *"The public must be satisfied that publicly-funded universities, as with any other public authority in receipt of public funding, are properly accountable, adopt systems of good governance and can inspire public trust and confidence in their work and operations. The FOIA, by requiring transparency and open access, allows the public to scrutinize the actions and decisions taken by public institutions. Failure to respond or to respond properly to FOIA requests undermines public confidence in public institutions. [...] The fact that the FOIA requests relate to complex scientific data does not detract from this proposition or excuse non-compliance. The public, even if they cannot themselves scrutinize the data, want to ensure that there is a meaningful informed debate especially in respect of issues that are of great public importance currently and for generations to come."* [66,67]

5.7) QMUL is part of a university-led campaign to weaken or avoid the FOIA

QMUL's strong resistance to disclosing trial data, and the retrospective reliance on S.22A, can be viewed in the context of a campaign by universities wanting to avoid public scrutiny.

There is tension between the FOIA and the universities who lobby to be exempted. In April 2012, The Constitution Unit (University College London) presented a seminar on 'Freedom of Information and Universities'. There was an increasing drive to open up research, including data archives and the publication of raw data. While some universities had concerns about the FOIA, there was a scarcity of evidence to support those concerns, and calls to remove higher education institutions from the FOIA could instead cause damage to universities' reputation. [68] FOI officers working in higher education institutions in the UK commonly report "recalcitrance" from staff as a major problem when trying to comply with the FOIA. [69]

The News Media Association, representing most UK newspaper publishers, warned that exempting universities from the FOIA would remove £4B/year of taxpayers' money from public scrutiny. They questioned the alleged burdens of the FOIA, and their position is that a combination of influence wielded by universities and the public funding they receive *"makes universities precisely the kind of institution that FOI was intended to render accountable"*. [70] In January 2016, Jack Straw (part of the five-person FOIA Commission) announced that they will not propose exempting universities from the FOIA and that there was no prospect of exemption. [71]

QMUL has previously lobbied members of parliament to change the FOIA to make their research data much more difficult to access. [72] Professor Peter White later claimed: *"The PACE trial has also played a small role in helping to amend the FOI Act for the better. From 1 October, current research will be exempt from the FOI Act so long as it can be shown that release of that data will be*

63. https://ico.org.uk/media/for-organisations/documents/1151/datasets-foi-guidance.pdf
64. http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3845048
65. http://www.ucl.ac.uk/constitution-unit/research/foi/foi-universities/foi-unis-conunit-seminar-12apr2012.pdf
66. http://www.foiman.com/archives/456
67. http://www.publications.parliament.uk/pa/cm200910/cmselect/cmsctech/387/38706.htm
68. http://www.ucl.ac.uk/constitution-unit/research/foi/foi-universities/foi-unis-conunit-seminar-12apr2012.pdf
69. http://www.ucl.ac.uk/constitution-unit/research/foi/foi-universities/he-foi-officers-survey-report.pdf
70. http://www.pressgazette.co.uk/university-sectors-bid-be-exempt-foi-would-cloak-%C2%A34bn-public-expenditure-secrecy-nma-warns
71. http://www.telegraph.co.uk/news/politics/12121015/FOI-commission-will-not-propose-exempting-universities-from-law-despite-proposals-from-ministers.html
72. http://www.bbsrc.ac.uk/documents/140606-annex1.pdf (p33-34)

prejudicial to the conduct of the research." [73] White has repeatedly complained about the burden of the FOIA and the alleged damage that it can cause to research e.g. recently arguing to the FOIA Commission reviewers that no current protection is strong enough to protect 'controversial research' such as the PACE trial, so universities should therefore be removed completely from the FOIA. [74] He failed to mention the existence of valid concerns, implied that activism typically involves harassment and abuse, and described the worse example of "damage" to the PACE trial as:

"Perhaps most damaging of all have been requests by two trial ex-participants to 'destroy' all their data collected on them during the trial because of their concern that the data will not be held securely and confidentially, something we promised them to do as part of their giving informed consent. [...] Section 22a of the Act is insufficient protection for science into controversial subjects, [...] We need science in the UK to be protected or it will continue to be damaged as this trial has been (other examples include climate change science, and research into the health effects of tobacco). Exempting Universities from the FOIA would achieve that."

As part of the consent form, participants could withdraw consent whenever they wanted. Concerns about data security and confidentiality may have arisen not due to fears of disclosure under the FOIA but from other information about how the PACE trial was conducted (see Part 2.6 on "Alternative explanations for participants' concerns with confidentiality").

After February 2011, the FOIA requests QMUL received in relation to the PACE trial were mostly for trial data and were prompted by highly contentious changes to the published trial protocol. Without disclosure of the disputed information, the public may never know the main trial results as pre-specified in March 2007, and the misleading claims of "recovery" will remain uncorrected. QMUL refuses requests for those results and has stated it has no intention to publish them. While QMUL's lobbying efforts to be exempted from the FOIA are framed as "protecting research", it would conveniently allow QMUL to minimise scrutiny from the growing number of academics, researchers, scientists, journalists, patients and advocates who express concern about how the PACE trial was conducted, analysed or reported (see Part 2.9b-c, Part 6, Part 7).

In an apparent attempt to marginalise or de-legitimatise these concerns during the ICO's investigation for FS50565190, QMUL misrepresented the arguments, beliefs, and motives of those who express such concerns; by unfairly dismissing them as misguided extremism stemming from prejudices against psychological or behavioural interventions; and also by misconstruing or conflating these concerns with one-sided, outdated, and sensationalist accounts of an alleged vexatious "campaign" aimed to discredit and harass research(ers). Elsewhere, QMUL and Professor Peter White repeatedly encourage or promote the view that asking critical questions, submitting FOIA requests to resolve unanswered questions, and posting criticisms of the trial, are in general, part of the alleged campaign or a form of "harassment"; without fair consideration or concession for the validity of the arguments, or the possibility that QMUL made significant mistakes (see Part 7). Similarly, QMUL attempts to associate me with this alleged campaign because I (independently) expressed concerns about the changes to the published trial protocol. QMUL's inaccurate speculations about my beliefs and motives are inconsequential to the exemptions relied upon.

Research with a highly controversial impact on the lives of millions of patients worldwide is likely to attract more critical attention than lesser claims [75], and the alleged bad behaviour of a few

73. https://www.actionforme.org.uk/uploads/pdfs/cmrc-2014-conference-report-final.pdf
74. https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/487271/Online_Responses_CitizenSpace.xls
75. http://www.publications.parliament.uk/pa/cm201012/cmselect/cmsctech/856/85602.htm

individuals is irrelevant to the rights of millions of patients. Many concerns about the PACE trial are valid and it is wrong to pretend that they are similar to funded campaigns for climate change denialism, tobacco industry interference with the science on the effects of smoking, etc. QMUL's assertions do not negate the valid concerns raised about the PACE trial, and such concerns need to be respected in order to move the debate forward. It is paramount that data costing £5M of public funding to produce is explored in the maximum practical extent. It is unfortunate that there are many barriers preventing this, despite the importance to millions of patients.

It is plausible that refusals to disclose trial data, and the failure to sufficiently address the problems that resulted in this request being submitted in the first place, is causing reputational damage to QMUL and fuelling further distrust. It is also contrary to the growing trend of increased transparency and open data in the wider research community. S.22A should not be used to suppress trial results, hinder debate, avoid necessary scrutiny, or prevent corrections. QMUL is not adhering to the letter and spirit of the FOIA legislation by refusing this request.

5.8) The public interest favours disclosure even if S.22A was to be applied

S.22A is subject to a public interest test, which strongly favours disclosure, and outweighs the minimal risks to the research programme or any personal desires to prevent re-analysis. For QMUL not to disclose the disputed information is likely to be detrimental to the PACE programme, because the widespread doubt, distrust and speculation over the results can be resolved only with disclosure. There is growing awareness in the wider research community that increased access to anonymised, individual patient data is necessary for the proper scrutiny of published research. As QMUL has failed to demonstrate an accurate understanding of the concerns about the trial, it is doubtful that they are in a position to fairly consider the public interest in disclosure (see Part 6).

Part 6: Why the balance of public interests favours disclosure

This is a response in the event that the public interest test is applied.
This section will be **Addendum 1**, an external document (pending):
“Alem Matthees' Response Addendum One”.

Part 7: Context for activism and allegations of harassment

This provides context if claims about 'harassment' have any bearing.
This section will be **Addendum 2**, an external document (pending):
“Alem Matthees' Response Addendum Two”.

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