FIRST – TIER TRIBUNAL

GENERAL REGULATORY CHAMBER

Information Rights

Appeal Number:	EA/2015/0269
Appellant:	Queen Mary University of London
Respondent:	The Information Commissioner
Second Respondent:	Alem Matthees

Before:

Mr. Brian Kennedy QC (Tribunal Judge)

Professor Darryl Stephenson (Tribunal Member)

Mr. Nigel Watson (Tribunal Member)

Hearing: the Residential Property Tribunal, 10 Alfred Place, London, WC1E 7LR, on 20- -22 April 2016.

Appearances:

Timothy Pitt-Payne QC of counsel for the Appellant.

Rupert Paines of counsel for the Respondent

Subject matter: Freedom of Information Act 2000, and the engagement of the exemptions under ss22A, 40, 41 and 43 and the application of the public interest test where applicable.

DECISION:

The Tribunal, by a majority, upholds the decision notice dated 27 October 2015 and dismisses the appeal.

REASONS

Introduction:

1. This decision relates to an appeal brought under section 57 of the Freedom of Information Act 2000 ("the FOIA"). The appeal is against the decision of the Information Commissioner ("the Commissioner") contained in a Decision Notice ("the DN") dated 27 October 2015 (reference FS50565190), which is a matter of public record.

2. The Tribunal Judge and lay members sat to consider this case from the 20-22 April 2016 and deliberated at a later date.

Factual Background to this Appeal:

3. Full details of the background to this appeal, Mr Matthees request for information and the Commissioner's decision are set out in the Decision Notice and not repeated here, other than to state that the request was for a selection of patient-level data ("the disputed information"- where each line of data is the data of an individual trial participant) from the results of a long-running clinical trial (the PACE trial"). The PACE trial tested the effectiveness of four of the main treatments available for people suffering from chronic fatigue syndrome ("CFS"). In his DN, the Commissioner ordered the disclosure of the disputed information. This appeal concerns the question of whether disclosure of the disputed information held by the Appellant public authority, Queen Mary University of London ("QMUL"), engages the exemptions in ss 40, and41 of the FOIA.

4. The request for the disputed information was made, by Mr Matthees, to QMUL on 24 March 2014, and they claimed that the aforementioned exemptions applied, and refused disclosure.

5. ISSUES:

Mr Matthees specifically sought anonymised data from the clinical trial concerning CFS. QMUL refused, arguing that disclosure would prejudice its research. The Commissioner ordered disclosure, as the participants could not be identified from the requested data and therefore the data was not personal information and there would be insufficient prejudice or detriment caused by disclosure.

The issues for this appeal are;

a) Should an exemption be applied retrospectively?
b) Is the requested data personal information, and is there evidence that participants could be identified from the requested material?
c) Would disclosure cause sufficient prejudice to QMUL's research programmes, reputation and funding streams to refuse disclosure?

6. HISTORY AND CHRONOLOGY:

2002	PACE clinical trial on chronic fatigue/ME commences
2009	Trial closes to recruitment
February 2011	Results paper published in The Lancet
Mid-2012	Follow-up research completed
24th March 2014	Mr Matthees request to QMUL
22nd April 2014	QMUL refusal, citing ss40(2) and 41 FOIA
18th June 2014	Mr Matthees request for internal review
16th Sept. 2014	QMUL review maintains refusal to disclose
15th Dec. 2014	Complaint to the Commissioner

7. RELEVANT LAW:

Section 22A Information derived from a programme of research

(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).

(2) The duty to confirm or deny does not arise in relation to information which is (or if it were held by the public authority would be) exempt information by virtue of subsection (1) if, or to the extent that, compliance with section 1(1)(a) would, or would be likely to, prejudice any of the matters mentioned in subsection (1)(b).

Section 40 – Personal Information

(1) Any information to which a request for information relates is exempt information if it constitutes personal data of which the applicant is the data subject.

(2) 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.

(3) 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.

Section 41 – Information provided in confidence

(1) 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.

Section 43 – Commercial Interests

(2) Information is exempt information if its disclosure under this Act would, or would be likely to, prejudice the commercial interests of any person (including the public authority holding it).

8. THE COMMISSIONER'S DECISION NOTICE:

Section 22A Exemption

QMUL stated that the data from the PACE research continues to be analysed with a view to publication of further papers, despite the closure of the trial to recruitment in 2009 and the follow-up was concluded in 2012. The Commissioner noted that the request was made before the s22A exemption came into effect. QMUL argued that s22A should be applied retrospectively as there was no 'manifest injustice' to retrospective application but rather it would keep the decision in line with Parliament's intent to protect the public interest in preventing prejudice to research or research participants. The Commissioner rejected this argument, noting the general rule against retrospectivity, the lack of an express provision to the contrary in s22A, and the fact that QMUL had not only refused the request but also upheld that refusal in an internal review prior to the commencement of the section. (In essence, this Tribunal accept and adopt this reasoning and reject the appeal under s22A see below.)

Section 40 Exemption

QMUL Arguments

- Requested data is sensitive personal data derived from living individuals, and Mr Matthees had asked the distinct variables to be linked by requesting the formatting be one row corresponding to one trial participant.
- The data cannot be satisfactorily anonymised if one considers the 'motivated-intruder risk' – the individual could self-identify from the linked variables, and given how small and active the 'community' of ME sufferers is there exists a risk that other ME sufferers could identify trial participants.

- QMUL has no permission from participants to publish data, and to require disclosure would damage trust and jeopardise future studies, pointing to a participant who had withdrawn consent for their data to be used after the close of the trial following a previous FOIA release. It also cited medical confidentiality and Article 8 ECHR.

- QMUL acknowledged that the majority of responses in the data were self-reports rather than objectively measured, but stated that people would be aware of their own responses. It highlighted what it described as "*a fairly small, but highly organised, very vocal and very damaging group of individuals who have...actually hijacked this agenda and distorted the debate so that it actually harms the overwhelming majority of patients...[They] actively seek to identify and attack those who are associated with the PACE trial*".

- NHS guidance emphasises that in health data the boundaries between personal/anonymised and non-personal data are unclear and "even the lowest risk publication carries significant risk". It was not in the public interest to jeopardise important medical research by ordering publication without ethical or security controls

The Commissioner's Arguments

The information is not personal information and s40(2) does not apply:

- It is unclear why satisfactory anonymisation was impossible when Mr Matthees has specifically excluded the personalised PIN references of participants from his request.

- There is no evidence that a motivated intruder could identify participants. Under the ICO Guidance a motivated intruder is **not** assumed to have any prior knowledge, specialist knowledge or equipment or to resort to criminality to access data.

- Whilst it is possible that some participants could self-identify, this is insufficient to label them 'identifiable' under s40(2). Identification is more than making an educated guess about the identity.

Section 41 – Information provided in confidence

QMUL Arguments

- Data was supplied not only under the traditional doctor-patient relationship but, additionally under a medical trial, which requires explicit consent.

- Disclosure would cause participants damage and distress, and compromise QMUL's ability to attract research funding in future.

The Commissioner's Arguments

As QMUL still had not explained how the data could lead to the identification of any individual, there would be no invasion of privacy in disclosure and therefore no breach of confidence.

Section 43(2) – Prejudice to commercial interests

QMUL Arguments

- Disclosure might affect QMUL's ability to attract funding for further research which would therefore damage the university's reputation and its ability to recruit high quality staff and students.

- It would affect recruitment of participants for future trials, damaging QMUL's ability to conduct further research.

- Failure to honour the explicit agreement with participants to keep the data confidential and use it only for research purposes would undermine trust in

investigators' intentions and potentially discourage participants from partaking in future or follow-up research.

- Publicity surrounding disclosure would cause anxiety to participants, particularly when one considers the potential hostility that could be shown to them by certain groups.

- Two participants had withdrawn their consent following the disclosure of some 600 pages of material including details of around 50 serious adverse events and reactions recorded during the trial. This caused a delay of four months in the project and increased costs.

The Commissioner's Arguments

- The Commissioner accepts that there is a potential prejudice to commercial interests that is not trivial or insignificant.

- The Commissioner accepts that there is a possibility that disclosure could deter future participants, but there is insufficient evidence that disclosure would be likely to result in the withdrawal of a sufficiently significant number of current or future participants to have an adverse effect on future research, reputation or funding.

- There is insufficient evidence that participants could be identified.

9. APPELLANT'S GROUNDS OF APPEAL:

GROUND 1: Section 40(2) – release of personal data that would breach data protection principles

Personal Information

Individuals could be identified in "at least" three ways:

(1) Participants could self-identify, and the Commissioner did not explain how this was insufficient to establish that this was personal data;
(2) Those with detailed prior knowledge of participants (such as friends, family or medical practitioners) could identify them; or
(3) Motivated intruders (such as campaigners or journalists) could identify participants and link this data to other information previously released.

The data is pseudonymised, not anonymised, and therefore is likely to constitute personal data. The data has "individual-level granularity" that gives rise to the "relatively high risk" of re-identification.

Data Protection Principles

One must consider whether disclosure to the world at large would breach data protection principles, not disclosure to this requester.

Principle 1 – Fair and Lawful Processing

Disclosure is unfair as it contravenes the legitimate expectations of confidentiality as explicitly set out in the research consent forms. It would cause unwarranted distress to participants and open them to criticism or harassment. The interests of the participants should take precedence. This data is sensitive personal data as it relates to the physical or mental health or condition.

Principle 2 – Purpose for collection and prohibition on further processing

Disclosure would permit the use of the information for a purpose incompatible with the purpose for which it was collected.

GROUND 2: Section 41 – Breach of Confidence

The information is presently confidential and relates to a particularly sensitive medical condition. It was imparted in a confidential doctor-patient circumstance with the additional confidentiality commitment in the consent form. Unauthorised disclosure would be to the detriment of participants. Even if the Commissioner

was correct in holding that identification was not possible, disclosure is still exempt under s41 as it would contravene a legitimate expectation of confidentiality that has nothing to do with privacy. Given the large amount of information about the PACE trials already in the public domain, there is no interest in disclosure that would outweigh the interest in maintaining confidence.

GROUND 3: Section 43(2) – Prejudice to commercial interests

Disclosure prejudices commercial interests in three ways: withdrawal of consent of existing participants; deter current participants from participating in long-term follow-up studies; and deter other individuals from taking part in future research. The withdrawal by two participants shows this prejudice is not merely speculative.

GROUND 4: Section 22A

There is no universal rule that statutory amendments cannot have retrospective effect, and in this instance retrospectivity would not impair the requesters vested rights or impose new liabilities on him. The requirements of s22A are clearly met as the information was obtained in the course of a research programme that is continuing with a view to further analysis and publications. At the time of the request QMUL was applying for funding for a long-term follow-up trial, and disclosure would prejudice both this and the present research by potentially inducing participants to withdraw.

GROUND 5 – Discretion

The Commissioner has the discretion even where information has been withheld in breach of FOIA to decline to order disclosure, and as s22A would apply if the request were made now this is sufficient to allow the Commissioner to exercise his discretion in this regard.

10. THE COMMISSIONER'S RESPONSE:

Mr Matthees' concerns relate to the methodology of the PACE trial, in particular that the criteria for 'recovery' following treatment are inappropriately defined or altered.

Ground 1 – Personal Data

The Commissioner does not dispute that the data relates to living individuals, but maintains that anonymization is plainly capable of rendering those individuals non-identifiable for two reasons:

(i) The pool of participants is large, and the incidence of chronic fatigue/ME in the general UK population is around 1%, therefore the class of potential trial participants 'vastly exceeds' the number of actual participants, rendering identification realistically impossible;

(ii) The information is not directly linked to the individuals, as it comprises wide-ranging scores derived from participants' self-reporting.

Dealing with QMUL's three routes to identification:

(1) Participants could only self-identify if they had access to their own data/responses, and it is not obvious that this is the case. In any event self-identification using knowledge of one's own personal circumstances is insufficient for the data to be deemed personal, as identification for the purposes of the Act must be able to be made by a third party.

(2) It is not reasonably likely that medical practitioners would seek to identify individuals, and friends or family are unlikely to be able realistically to identify participants.

(3) There is still no evidence from QMUL as to how a motivated intruder could link the variables in the data to other information previously released.

The point made about granularity and risk is a generic point that there exists in all instances a spectrum of risk, but the test for the Tribunal is whether or not anonymization will be effective in any given factual instance.

However, the Commissioner accepts that if the Tribunal finds that identification is possible and the data is personal data, then the data would be deemed sensitive under s.2(e) DPA and disclosure would be barred.

Ground 2: Breach of Confidence

As identification is realistically impossible, there would be no breach of confidence. To argue that any disclosure of information provided in a professional relationship of trust, even if that information is anonymised leaving no real prospect of identification, is a breach of confidence runs directly contrary to the ruling of Simon Brown LJ in *ex p Source Informatics Ltd* [2001] QB 424.

Ground 3: Prejudice to Commercial Interests

The Commissioner accepts that attracting research funding is a legitimate commercial interest, but disputes that disclosure would cause a sufficient number of participants to leave the trial and jeopardise QMUL's reputation. The previous data releases were of a larger scale and did not result in withdrawals of a scale that would jeopardise the quality of the trial. The public interest would favour disclosure given the significant public debate surrounding the PACE trial.

Ground 4: s22A

The general presumption against retrospectivity is uncontroversial and frequently applied as a matter of statutory construction, only to be displaced by contrary indicators of legislative intent. There is no such intent evidenced in this instance. In any event, disclosure of anonymised data would not prejudice the research programme within the meaning of s22A(1)(b)(i).

Ground 5: Discretion

The case of *ICO v HMRC & Gaskell* [2011] UKUT 296 (AAC) held that the Commissioner's discretion should only be exercised in exceptional circumstances when, given a change of circumstances, disclosure would be unlawful, impossible or wholly impractical. Here, there is no mandatory prohibition and the general right to information takes precedence. (As indicated, this Tribunal accept and adopt this reasoning and reject the appeal under s22A see below.)

11. MR MATTHEES' RESPONSE:

Purpose of disclosure

a) To overcome the 'breakdown in trust' between QMUL and the public
b) To examine and re-analyse recovery and subjective scores compared with objective measures of function

Ground 1: personal data

The request was not for pseudonymised but anonymised data at the point of disclosure, and the anonymised data gives rise to no reasonably likely risk of identification. The data do not contain personal identifiers that could undermine anonymization such as location, gender, ethnicity etc. Rather the information is generic, non-unique and based on variable outcomes that are difficult to repeat precisely (e.g. walking test). Many of the scores are *calculated* from questionnaires filled in by participants and so are distinct from the personal responses of the participants, making extrapolation of identity highly unlikely. In fact, a 2008 amendment to the PACE trial protocol justified not attaining additional consent from participants in using their data in an ancillary study precisely because their details were "anonymised by the trial nurse on all

documentation so that only she may identify them" and therefore all data "will be completely anonymous".

It is highly unlikely that the withdrawal of the two participants resulted from the ability to identify them from disclosed anonymised data. QMUL has not provided evidence those participants who have identified themselves to the public or the media as participants have been targeted or harassed as a result. Rather, their withdrawal is more likely to have been motivated by :

a) public criticisms of the PACE trial's data security published by Prof. Malcolm Hooper detailing an inadvertent leak of names and addresses of certain participants, the theft of a digital audio recorder and reports from participants that they were repeatedly questioned on their welfare/benefits claims and insurance payments; or
b) a series of articles published by David Tuller on the Virology Blog in which it was claimed that researchers had undeclared links to insurance companies.

There have been no instances in which participants have been identified by anyone other than themselves, and those that did self-identify were not subject to criticism or harassment. Those participants who do fear identification have been misled by QMUL's substantial exaggeration of the risks of re-identification and misrepresentations of the arguments and motives of those making legitimate criticisms of the PACE trial. Mr Matthees cites numerous guidelines from the NHS, GMC and ICO to support his contention that de-identified data is not confidential.

Mr Matthees argues that the data in any event is not sensitive, and that the wider research community is heading towards open data.

Ground 2: Breach of Confidence

The Universities UK website advises that s41 is of doubtful application to anonymised medical data even when confidentially obtained, and the NHS Health Research Authority similarly states that it is a common misconception that the DPA always requires consent to data processing, as medical data can be used for any medical research purpose. The information sheet given to participants explicitly states that their data may be viewed by other researchers, in the course of an audit, and further the FINE trial published similar data without DPA concerns.

Ground 3: Commercial Interests

QMUL overstated the risk of withdrawal of participants, and they risk greater reputational damage by their failure to acknowledge or address the concerns that prompted this FOIA request than they risk by disclosure. S43(2) does not protect non-commercial reputational interests, such as unfavourable results from re-analysis of the data. In any event the public interest overrides any potential commercial prejudice, given the growth of open data initiatives and the concern that researchers could potentially suppress unfavourable results.

Ground 4: s22A

There is no convincing reason why s22A should be applied retrospectively. The data collection was complete by January 2010, and multiple papers have been published using it since February 2011. The main analyses have been published, and other aspects are now being considered using data that is not the subject of the instant request. S22 and s22A were intended to protect research by preventing premature disclosure – this is not necessary here. The five-year follow-up mentioned by QMUL was confirmed by PACE as **not** being the same project, and Mr Matthees strongly suspects that participants would have already signed up and their data already collected by now. He makes certain criticisms of the usefulness of long term follow-up data regarding treatment contamination and interventions encouraging different treatment

methods thereby destroying the randomisation of the trial. He further contends the QMUL have lobbied Parliament to amend FOIA to restrict access to their research data in the context of a 'campaign by universities wanting to avoid public scrutiny'.

12. APPELLANT'S REPLY:

Ground 1: Personal Data

QMUL accepts that neither source of guidance that it cited in the Grounds for Appeal is binding authority, but they are persuasive. It distinguishes situations in which disclosure relates to statistical information from the present instance of trial results at an individual patient level.

Ground 2: Breach of Confidence

The *ex p. Source Informatics* case does not support a general proposition that a duty of confidence will not be breached by disclosure of personal information unless there is a possibility that the information can be linked back to the individual concerned. Rather, the scope of any relevant duty of confidence depends on the circumstances in which the information was confided. QMUL argues that disclosure would breach specific assurances of confidence even if it is wrong that there is a risk of identification.

Ground 3: Commercial Interests

Risk of withdrawal of participants exists even if QMUL is wrong regarding risk of identification. There is no explanation as to how disclosure would assist the public debate surrounding the issue, as further multiple analyses could produce misleading results. The requested information alone would not be adequate for any meaningful re-analysis, and any further requests for disclosure to allow for analysis would increase the risk of identification. QMUL accepts that minor

changes were made to the way pre-specified outcome measures were analysed as compared to the pre-trial protocol, but states that these were unremarkable and made before data examination with the approval of the independent steering committee.

13. WITNESS EVIDENCE:

QMUL

Professor Trudie Chalder – Dept. of Psychological Medicine, King's College London

Experts cannot agree whether ME and CFS are the same condition. Professor Chalder developed a cognitive behavioural therapy (CBT) approach and tested it, first in open trial then in randomised controlled trial.

PACE Trial

The PACE trial investigated 4 treatments for CFS: (i) specialist medical care (SMC) alone; (ii) SMC plus adaptive pacing therapy; (iii) SMC plus CBT; and (iv) graded exercise therapy. SMC is doctor-dispensed general advice about managing the illness with specific drug treatments for insomnia, pain etc. Pacing therapies involve the patient learning to optimally adapt to the limitations imposed by their illness. CBT focuses on developing a consistent approach to activity develop healthy sleep patterns and challenge unhelpful thoughts. Graded exercise is establishing a baseline of consistent activity and regular sleep patterns before incrementally increasing time and intensity of exercise.

The research was funded by a grant from the Medical Research Council and the treatment by the NHS, and the trial was reviewed by academic experts and amendments made following collaboration with the patient organisation Action for ME. Participants were recruited from specialist outpatient clinics in England and Scotland. Consent was obtained first for baseline assessments and then for the full trial, giving them a week between each consent stage to

consider their participation. The consent forms assured 'strict confidentiality' but stated that participants' GPs and medical professionals will be informed about their participation and other researchers from QMUL, other universities or other organisations may view their data for audit purpose. Specific consent for this was obtained in the consent forms.

One participant withdrew owing to concerns about confidentiality, and the main analysis had to be restarted. Another expressed concerns about confidentiality but was persuaded not to withdraw their data. Many participants expressed concerns about confidentiality before consenting to the trial. 8% of participants dropped out of treatment. Researchers concluded that CBT and GET were moderately effective and safe treatments.

It is acknowledged that QMUL received 'many requests' for PACE trial patient data and had supplied anonymised data to independent scientists as part of "normal research collaboration" under formal confidentiality agreements, but refused to publically release the information owing to concerns about misuse of the data such as through inadvertent personal identification.

(N.B. This Tribunal is of the view that QMUL cannot rely on the strict wording of the consent forms regarding confidentiality if they are happy to share the anonymised data with independent scientists as research collaboration rather than an auditing situation. In our view, they are tacitly acknowledging that anonymization is effective, or else they would be in breach of the consent agreement and the DPA principles.)

Professor Chalder notes particularly vociferous criticisms posted on the Phoenix Rising forum of the trial results and subsequently of particular researchers, and a promotion of the use of FOIA as a weapon. She attributes the basis of these criticisms as the misconception that CBT as a treatment assumes that CFS/ME is perceived as a mental illness.

The previously disclosed PACE trial data was released by the NHS West Midlands Research Ethics Committee, and it is not clear as to whether the forms setting out the severe adverse incidents for participants were disclosed.

(This Tribunal notes that this is contrary to QMUL's submissions to the Commissioner in which they stated that these were disclosed.)

Professor Chalder refutes Mr Matthees' claims that the definition and criteria for recovery were weak or inappropriate, and the criteria for recovery were only amended after the original protocol as they were deemed to be too conservative. She believes that self-identification would be possible if the individual had scored extreme values at the end of the trial or if they had been unable to complete the walking test, and similarly identification by family or friends if the individual had shared details of their participation with them. Regarding motivated intruders, activists have asked for participants to share their experiences and indicated their desire to track down participants in order to circulate negative experiences. Patients have approached Professor Chalder with their concerns about going public with any improvements after CBT/GET for fear of harassment by activists. She extrapolates this concern to future trials for other 'stigmatised conditions' and to harassment and hostility towards researchers.

Funding of the follow-up trial has been agreed and will begin once ethics and NHS approvals are obtained, and Professor Chalder has concerns that disclosure would break the promise of confidentiality and discourage participation in the follow-up trial. Disclosure of the data would prejudice publication of further papers as Mr Matthees could publish the data and it is rare for data to be published twice.

Professor Steven Thornton – Vice-Principal (Health) of Barts and London School of Medicine and Dentistry, QMUL

It is generally accepted that data from clinical trials be made available for further analysis but only to *bona fide* researchers with a pre-specified statistical analysis methodology who are prepared to publish data once analysed and are part of a research organisation, and where confidentiality of patients is assured. The most important reason to restrict the dissemination of data in this way is to prevent spurious results from analysis without pre-specified methodology or peer reviews.

Anonymisation may not be effective regarding people with unusual or rare conditions or in a small population (here, CFS sufferers are <1% of the general population), and consent forms would need to be redesigned to warn potential participants. Should disclosure jeopardise participation in trials, it would damage the commercial interests of QMUL as a research institution in a highly competitive field.

Professor Ross Anderson – Professor of Security Engineering, University of Cambridge

BMA's adviser on safety, and privacy of clinical information systems.

There is a 'stark contrast' in what Professor Anderson terms the 'hopeful view of anonymisation' in the ICO's Code and the 'emerging scientific consensus' that anonymization does not eliminate the risks of re-identification. The NHS' disclosure of anonymised patient records under the care data scheme caused massive outcry when it was revealed that an identifier was included that in most cases contained the patient's postcode and date of birth, allowing in some cases identification of individuals who had a particular treatment on a particular day with a particular provider. Postcode plus date of birth is sufficient to identify 98-99% of the population. When two seemingly disparate data sets are linked anonymisation can fail.

(This Tribunal notes that Mr Matthees data request specifically does not require anything of this nature to be disclosed and specifically asks that it be anonymised.)

Professor Anderson draws parallels between CFS activists and animal rights pressure groups in raising concerns about the potential for a serious risk of violence to participants and researchers, and also in the prospect of using 'insiders' to threaten or undermine the project. Threats exist to participants and researchers from activists outwith the jurisdiction and beyond the practical reach of UK law enforcement.

As the participants were drawn from 6 outpatient clinics, this reduces the pool of potential participants from c.500,000 CFS suffers in the UK to the 3,158 individuals attending those clinics. If the activists can access HES (Hospital Episode Statistics) data via an NHS insider or from the care data release, they can find out the postcodes and dates of birth of almost all of these 3,158 new diagnosed cases. There is sufficient information within the request to allow for the potential of identification.

(This Tribunal notes that this seems to be in relation to the information being made available to the patients on demand, so this identification is largely self-identification, and Professor Anderson acknowledges that most of the results are "less easily memorable" for patients than walking distance scores in the event that they have requested and been provided with them.)

Professor Anderson then goes on to clarify that 2 walking test scores would be sufficient, and that participants could tell their partner who could note it in a diary or post it on social media and that could be accessed by 'attackers', or the partner could make the information known maliciously to attackers following the breakdown in the relationship.

Professor Anderson disagrees with the Commissioner's proposition that incorrect identification or identification down to one of two is still sufficient privacy, citing the justifications of harassment and the potential threats to not only the participant but the erroneously included individual. The 'motivated intruder' test is too weak to be applied to the present instance, as it must be assumed that the 'attackers' will have access to NHS systems or at very least care data information. He describes The Commissioner's Guidance on anonymization to be mistaken and obsolete following the care data 'scandal'.

(This Tribunal notes Professor Anderson's witness statement and evidence strays substantially into comments on the law, the standard of proof and the applicability of ECHR principles of this issue, and the Commissioner's previous decisions regarding the definition of personal data, on one occasion differentiating the Commissioner's definition from that of 'normal people's understanding).

Dr Frances Rawle – Head of Corporate Governance and Policy, Medical Research Council

MRC funded the PACE trial through a research grant, but does not own or retain any rights to the data generated but expects all data to be processed in accordance with the consent given by participants. The PACE trial was not obliged to submit to MRC a data management plan as it was approved prior to the commencement of that policy, but the MRC would expect all requests for data to be considered by the research team and implemented in such a way as to guarantee compliance with the terms of the participants' consent.

Re-identification has been a concern for an advisory group on data access established by funders of public health and genetics research, given the widening use of administrative data and individuals releasing more information about themselves on social media. CFS/ME is currently under-researched, and uncontrolled disclosure of information could damage participation of patients in future research.

ALEM MATTHEES

JOINT STATEMENT FROM ACADEMICS AND CLINICIANS

12,000 people including researchers, academics, patients and journalists have signed a petition calling for a release of the PACE data and an independent review of the trial following concerns regarding the trial. The public interest significantly outweighs the overstated risks, as it will help to resolve the controversy over the trial results and alleviate the distress of the patient community.

Kenneth Friedman, Assoc. Professor Pharmacology and Physiology (retired), New Jersey Medical School

Comparable situation in USA where the data gathering was publicly funded is that the data is made public. The concerns about misinterpretation of the data are disingenuous and overstated, and there is nothing to prevent the researchers joining the debate to correct any perceived misrepresentations. ME/CFS patient community are 'knowledgeable' and 'scientifically-savvy' and efforts to keep data private have historically caused more harm than good, drawing comparisons with the AIDS epidemic in the USA.

Jonathan Edwards – Professor Emeritus in Connective Tissue Medicine, UCL; Director of Phoenix Rising website

PACE trial was poorly designed, poorly executed and inappropriately interpreted leading to his conclusion that the outcome was uninterpretable or that none of the treatments differed importantly in effect. The trial can be criticised for lack of treatment blinding combined with subjective evaluation, and the nature of CBT means it is almost impossible to separate placebo from specific effects, leading to consistent over-interpretation of results.

Professor Edwards takes issue with the assertions that Phoenix Rising is allowing inappropriate behaviour, and further takes issue with the term 'activist' being used for its audience. He distinguishes highly motivated data requestors from those acting inappropriately or unreasonably. He accepts that certain individuals have expressed their frustrations with the misinterpretation of the PACE trial on the website in abusive terms, but this pales in comparison with four years of "intelligent and measured critique" provided by the other patients. Rather, the campaign to discredit or hijack the issue has come from the PACE authors and their colleagues in a series of attacks in review articles in the national press, online and in public presentations.

Dr Lily Chu

Increased sharing of clinical data has been advocated by the International Committee of Medical Journal Editors, and the US Institute of Medicine. It is especially important in the PACE trial where many clinicians, researchers and patients question the scientific validity of the trial. Confidentiality, scientific credit and logistical challenges are all surmountable.

14. SUPPLEMENTARY DOCUMENTS:

A number of press articles are included in which allegations of harassment are extensively detailed, but the excerpts from Phoenix Rising and the comments on the articles do not evidence this harassment.

At 4.7 an academic article by Paul Ohm suggests 5 factors for assessing the risk of privacy harm by information release and re-identification:

i) Data handling techniques
ii) Release to general public v release to trusted private partner
iii) Quantity of data to be released
iv) Motive of data recipients
v) Trust in data recipients

At 4.9 p813 the Royal Society report on Science as an Open Enterprise details ways in which sensitive data can be shared between researchers in secure sites known as 'safe havens' accessible only by authorised researchers. It recommends that personal data is only shared if necessary for research with the potential for high public value.

(The most important question for this Tribunal to decide is whether or not in this factual matrix the data can be sufficiently anonymised. Many of QMUL's supplementary documents and witness statements seem to be leaning towards the general proposition that regarding medical research databases of this type there can never be sufficient anonymization to prevent re-identification given advances in computer science and cross-referencing of previously disclosed databases. Whilst this is an important policy decision for this Tribunal to consider in regards to whether a decision on this would affect all future requests for similar information, it must only be considered in regard to this case, this data and the surrounding circumstances and it is in this light that we will only consider all the evidence and submissions before us in this appeal.)

15. QMUL FURTHER SKELETON 14TH APRIL 2016:

The PACE trial was met with general support from the scientific community, but 'highly critical' and 'vitriolic' patient/activist groups reacted to perceptions that the research suggests that psychological factors or treatments are appropriate for CFS/ME by trying to discredit the research. These are relevant and/or are fundamental when considering the implications of disclosure.

The question of identifiability gives rise to two issues:

i. What level of risk of identification must there be to constitute personal data
ii. What exactly is meant by 'identification'

QMUL characterises the Commissioner's position as that when the risk of identification is greater than remote the data is personal, and identification is only

relevant if there is a degree of certainty in the veracity of the identification that is more than an educated guess. In response, three points:

i. Even if the Commissioner's position is correct the data is personal;
ii. The Commissioner's approach is too narrow as it allows for an acknowledged privacy risk whilst still maintaining that the data is not personal – it should also cover cases "where an individual can be singled out as being a person to whom the information could very well relate";
iii. This broader approach is still relevant in whether disclosure interferes with privacy and therefore whether it amounts to a breach of confidence.

Regarding 'motivated intruders', they are strongly motivated to discredit the PACE trial and identification of participants could be the first step. Combining public information sources is essential in considering risk of identification, including the voluntary disclosure by participants themselves.
Disclosure would breach legitimate expectations of participants created by the assurances of confidentiality, would cause unwanted distress, would impinge upon their Art.8 rights and would not be in the public interest given how much information is already in the public domain. The public interest in achieving proper scrutiny of the research can be met by sharing the data for reanalysis with other researchers on a confidential basis. Disclosure would also involve processing sensitive information for a purpose incompatible with how it was obtained.

(This Tribunal find it difficult to see how this objection of 'incompatible processing' can be maintained given that the information is currently being released to other researchers for the purpose of further analysis, such as is being requested in this instance. Given the anonymised nature of the data there is no other conceivable use for the data than further analysis in this context, and the consent forms at no stage advised participants that their data could be shared with researchers not involved in the PACE trial except in circumstances of audit. This Tribunal will

consider all the evidence about identification in its assessment of potential victimhood for the purposes of Art. 8 or otherwise.)

QMUL widens the effect of disclosure on its commercial interests; it now argues that disclosure would undermine the entire ethical and regulatory framework for clinical research and deter future participation in clinical trials.

(This Tribunal is of the view that this must be an overstatement, as it seems previous FOIA disclosure of information relating to these trials did not have that apocalyptic effect. QMUL reiterates the argument that there is no universal rule that statutory amendments cannot have retrospective effect and while we accept this, this Tribunal finds there is a rebuttable presumption that they should not have retrospective effect. We further note that there is little by way of tangible evidence before this Tribunal of damage to the Commercial Interests despite this appeal. On the contrary, the evidence has shown that further funding has been obtained.)

16. COMMISSIONER'S FURTHER SKELETON 14TH APRIL 2016:

The Commissioner accepts that the question turns on whether anonymization is possible, and he argues that in this instance identification is an extremely remote possibility. Professor Anderson accepted that the information alone cannot identify participants, and his hypothesis that identification is possible through combining that information with NHS data (involving an NHS employee both having breached their professional, legal and ethical obligations and also having the skill and inclination to so do) is implausible:

a) Release does not include postcodes and dates of birth, and the *care data* release was not general but done under license presumably with stringent confidentiality requirements.
b) The notion of such a profound ethical and legal breach by an NHS employee is without warrant.

c) There is no evidence that friends or family of participants will have received [***much less, retained***] (our emphasis) the information.

The characterisation of an 'adversarial group' is a vast logical leap from critics "asking" former participants to share their experiences (as *per* Dr Chalder's statement).

The Commissioner reiterates that *ex. p. Source Informatics Ltd* held that anonymised data does not hold the same character of confidentiality as personalised information.

The Commissioner makes a distinction between participation in the trial (which is not a commercial interest) and the ability to attract funding (which is). He raises the following points about the concerns of a mass exodus of participants:

a) Participants have already consented to significant disclosure of non-anonymised information to other researchers for audit purposes or regulatory purposes;
b) A digital audio recording was stolen in 2006;
c) 2,000 pages of trial documentation has been released;
d) The Cochrane Review team received all the trial data;

And despite all of this, only one participant left the trial over confidentiality concerns. Prejudice is therefore at the lower end of the scale, and this significant and legitimate scientific debate over the trial would be significantly advanced by the release of the information. (This Tribunal note there is no explanation as to how it would be advanced, but we assume it would be through further independent analysis.) Mr Matthees below raises concerns that QMUL are restricting the registered researchers to whom they disclose the data upon request. (The evidence before us is not clear but if QMUL are cherry-picking who analyses their data from within the recognised scientific research sphere to only sympathetic researchers, there could be legitimate concerns that they wish to suppress criticism and proper scrutiny of their trial.)

The Commissioner reiterates the general presumption of non-retrospectivity that can only be displaced by contrary indicators of legislative intent (Here, we accept there are no such indicators.)

(Regarding discretion, we accept and adopt the Commissioner's assertion that it is a derogation from principles and must only be exercised in very limited situations where disclosure would be "unlawful, impossible or wholly impractical".)

17. FURTHER DOCUMENTS PROVIDED BY MR MATTHEES:

1. An open letter to the Lancet from scientists and clinicians raising concerns about the methodology and conclusions of the PACE trial.
2. Petition 'Misleading PACE Claims Should Be Retracted' with 12,000 signatures detailing specific criticisms of the trial, including altered recovery thresholds as compared with baseline trial eligibility thresholds and refusal to publish planned recovery analysis. It includes specific feedback from trial participants detailing varying levels of dissatisfaction with the trial.

Harassment of Participants by Activists

Mr Matthees notes that further participants have subsequently shared their experiences online and have received no harassment or negative responses and provides the hyperlinks to those. Criticisms have been directed exclusively at the trial, not the participants. The repeated use of the term 'activists' disparages patient groups critical of the PACE trial. Mr Matthees points to press releases from the Science Media Centre, a body working with PACE researchers, to the effect that they were "engineering the coverage" to "frame the narrative" in such a fashion to discredit those with legitimate criticisms as misguided extremists by sensationalising a small number of indefensible actions to the detriment of the

vulnerable wider patient 'community'. This has been highlighted by respected scientists, and clinicians (see p87-90/B7). Rather, no evidence of a 'silent majority' in support of the PACE trial has been put forward.

As for using FOIA as a tool to harass the researchers, Mr Matthees states that 39 FOIA requests have been made over the five-year period of the trial, which is less that one per month. Under ICO Guidance, similar requests from disparate requesters cannot be considered vexatious if they are asking for information independently on the same subject because of media or local interest, rather than acting in concert. QMUL's refusal to disclose anonymised data and their approach to criticism is largely responsible for the number of requests.

Data sharing with bona fide *independent scientists*

Mr Matthees questions QMUL's assertion that the data would not allow for "meaningful" re-analysis, stating it is incorrect and without explanation. He has asked for the "bare minimum" of data variables to allow for equivalent analyses to allow for the maximum chance of success in the granting of disclosure. His analysis proposals include comparing the self-reported improvement scores with the objectively measured walking scores.

He notes that in Professor Chalder's witness statement at para.67 PACE researchers have supplied *"requested, anonymised data to independent scientists, as part of normal research collaboration"*. This Tribunal notes this suggests an acceptance on Professor Chalder's part that anonymization can be sufficiently carried out for disclosure purposes. Professor Chalder states that disclosure to the Cochrane review does not count as disclosure to independent scientists as all three of the PACE principal investigators sat on the review panel. However, if it was indeed independent it shows disclosure outside the bounds of the research group (and by extension this Tribunal assume beyond the consent form authority) but independent scrutiny to deal with the manifold criticisms of the process would be consistent with participants' broad expectations of the scientific

process. He highlights that disclosure was refused to *bona fide* respected independent researchers such as Professor Ron Davies of Stanford University on the grounds that he was critical of the trial.

Mr Matthees makes the point that revenge-driven spouses would not need to identify their former partners from disclosed data – they would be in a position to 'denounce' them to the world for the participation in any event. He sees Professor Anderson's risk model as highly emotive and without foundation, possibly based on misleading information having been fed to him. He does not provide any mechanism for how HES datasets could be linked to the requested data as they do not contain any common variables. He adds that if no anonymization can be effective against malevolent insiders, then the data should never be collected or stored, let alone disclosed.

Public Interest in Disclosure

i) Concern expressed by academics, clinicians and scientists about the analysis and reporting in the PACE trial. Pp91-97/B7 and pp102-105 highlight scientific criticisms of PACE trial.
ii) Scientific importance of pre-publishing and adhering to trial protocols and then reporting on pre-specified outcomes to prevent post-hoc revisions and potential biases.
iii) Failure by QMUL to acknowledge or address criticisms.
iv) PACE trial researchers are causing distress and harm to patients by exaggerating their trial results.
v) Researchers are more likely to suffer reputational damage by their continued refusal to address criticisms and allow disclosure.
vi) 12,000 people have signed a petition calling for the retraction of questionable claims and disclosure of the data.
vii) Increasing trends of transparency and open data in the research community, especially when that research is publicly funded.
viii)All concerns of commercial interest and confidentiality are surmountable.

18. QMUL'S CLOSING SUBMISSIONS:

The requested information consists of a table giving linked information about a number of patients, and so is fundamentally different from aggregated or statistical information. Successful anonymization is difficult to achieve when information is at an individual level. Dr Rawle admitted that open access *could* be legitimate, but the limitations of consent are important and the MRC's approach clearly favoured controlled access (see p195/B7 for limitations of open access sharing and the benefits of controlled access).

Four types of harm can arise from disclosure:

i) Should anonymization fail, conclusions may be drawn about individuals.

ii) An individual could be identified as one of a group who may well have been participants, short of definitive identification, which is adverse in terms of individual privacy even if that information is not personal.

iii) Individuals suffering anxiety and distress for fear that they *might* be identified and/or disclosure may be contrary to their expectations.

iv) Individuals are exposed to a risk of future identification.

(This Tribunal note that this is all predicated on the inability to sufficiently anonymise the data. We note that QMUL accept that there is no evidence of any threats by activists of physical violence against participants but state that it is reasonable to expect that some campaigners will be strongly motivated to identify participants.)

Professor Anderson's evidence was that people have access to NHS records and there is an "obvious risk" that "activist groups" will recruit a "sympathetic insider" to access these records. (However this Tribunal notes that if there is no evidence of hostility towards participants, then this risk is far from obvious. Professor Anderson in evidence accepted that regarding the possibility of identification, one must take account of "*all the means likely reasonably to be used....to identify the said person.*" This we find however is not any conceivable

method of identification, only those likely reasonably to be used. The Tribunal must consider whether any individual is likely reasonably to have the means and skill to identify any participants, and also whether they are likely reasonably to use those skills for that purpose.)

Breach of Confidence

Coco v Clark [1969] RPC 41 shows that information can be confidential even if it has nothing to do with individual privacy. This disputed information has the necessary quality of confidence, and where it is shared it is done so under a confidentiality agreement. It gives rise to an obligation of confidence from the consent forms assuring confidentiality within the extended research team ***[cf. previous admission of sharing outside the strict terms of the consent forms]***. Disclosure would cause detriment through a departure from their expectations and privacy-related risks of identification (even if claims of identification are false).

Article 8

Failure to take appropriate steps to prevent unauthorised access to an individual's health data, even where the individual cannot prove that the information actually was accessed or disseminated in an unauthorised way, is a breach of Art.8: *I v Finland* (2009) 48 EHRR 31. DPA definition of 'personal data' must therefore be read sufficiently widely to protect that privacy, and the duty of confidence must be read in a manner that safeguards Art.8 rights.

ex p Source Informatics Ltd can be distinguished from the instant case as it involved disclosure to a specific individual rather than general publication, and there was no evidence about specific assurances given as to how the data would be used. It did not take place in relation to a matter of fierce public controversy with the attendant risk of anxiety and distress caused by fear of identification. It

would also trouble the consciences of those potentially required to disclose the information.

Prejudice to Commercial Interests

The risk of patients withdrawing over privacy concerns is not fanciful, as one patient has already withdrawn. Prof Chalder gave evidence that "quite a few of the patients she came across felt that it was frowned upon...that they had taken part in the trial" and that they were "nervous of acknowledging that they had had CBT or GET". The more patients that withdraw, the weaker the long-term follow-up conclusions will be.

S22A - arguments repeated as per previous submissions.

19. THE COMMISSIONER'S CLOSING SUBMISSIONS:

The question for the Tribunal is whether particular individuals are identifiable from the disclosed information. The Commissioner's Guidance does not require anonymization to be completely risk free, only that the risk is mitigated until it is remote. Identification from the disputed information is not reasonably likely, as it does not contain any fixed or direct identifiers. Dr Rawle confirmed this in her evidence. The Appellant argues that data is personal data if a small number of individuals could be identified therefrom. The Commissioner's position is that (a) it is necessary to be able to identify *"a living individual"* , i.e. one single individual and (b) that *I v Finland* does not change that position (– see Commissioner's closing submissions at paragraphs 15 – 16) and there was no anonymization issue raised therein. It is common case that the disputed information alone cannot identify individuals, and Professor Anderson's "rough guesstimate" of the likelihood that other information will be available is "remarkably unsophisticated logic".

Potential Identifiers

Self-identification, the Commissioner argues is irrelevant, as the test is for third-party identifiability. In any event he argues, there is no evidence that any participant actually retained their exact scores and information from the trial.

It is unlikely that close friends and family will be motivated intruders, and it is even less likely that they will have obtained the information in the first place, let alone retained it after the passage of years between the trial and the request, and certainly highly unlikely with the necessary precision to facilitate future identification.

The Commissioner asserts 'motivated intruders' evidence from Professor Anderson was accepted under cross-examination as an 'over-extension' from his personal experiences with completely unrelated animal rights activists – **see para.24 of the closing submissions**. Professor Anderson's "wild speculations" about the possibility of "young men, borderline sociopathic or psychopathic" attaching themselves to the PACE trial criticism "do him no credit". Nor do his extrapolations from benign Twitter requests for information to an "organised campaign" from an "adversarial group" show that he has maintained the necessary objectivity and accuracy that he is required to maintain. He does not distinguish between legitimate ethical and political disagreement, and the use of positions of access to confidential data. He stated that where there was legitimate disagreement one should assume that people will act in unlawful ways. This proposition that one should in every case assume the absolute worst about data disclosure is clearly neither sensible nor realistic. His admissions that he is part of a body (Foundation for Information Policy Research) that in his words "manufactures the ammunition...that privacy activists...fire at appropriate targets" shows his evidence to be not in fact impartial and in our view requires extreme caution in its consideration.

Contrast instead Professor Chalder's evidence when she accepts that unpleasant things have been said to and about PACE researchers only, but that no threats have been made either to researchers or participants. The highest she

could put it was that some participants stated that they had been made to feel "uncomfortable" as a result of their contact with and treatment from her, not because of their participation in the trial *per se*. There is no evidence either of a campaign to identify participants nor even of a risk of an 'insider threat'.

Combining Information sources to identify

Generic references to 'social media' and non-specific assertions that there is "so much information out there" are insufficient to assist in this appeal. There is no evidence that information regarding Serious Adverse Events has been disclosed. The care data information was anonymised and disclosed under license, and Professor Anderson was surprisingly reluctant to speculate on whether these licenses would contain confidentiality provisions. He and Professor Chalder both accepted that reidentification would require a very great deal of work. The most that could be achieved from NHS data alone would be the identification of those who had been screened for CFS at the relevant clinics in the 5 year period, but the Tribunal should be slow to assume that health workers cannot be trusted to abide by their legal and ethical obligations.

Ability to identify

Professor Anderson accepted it would be extremely difficult to identify individuals even from the collective information, which, given his approach to this should indicate the near-impossibility of reidentification.
Therefore it remains that there is no evidence before the Tribunal that it is reasonably likely that individuals could be identified.

Breach of Confidence

The *Source Informatics* case is clear that a disappointed patient cannot sue in confidence if anonymised information is disclosed. QMUL seeks to turn the law of

confidence from a law about confidentiality of information to a law about consent in relation to information.

It is clear from QMUL's sharing of the data with other chosen researchers that they do not slavishly and mechanistically adhere to the scope of consent in trial forms. The two MRC publications treat anonymization and consent as alternatives, and Dr Rawle accepted this in cross-examination (however Professor Chalder and Dr Rawle say that the current position has now changed). The scope of the consent given does not prohibit disclosure, as Professor Chalder accepted the consent forms permit the use and publication of the information with no limitation on the way it can be used and published, so long as no identifying information was released.

Commercial Interests

The threat of withdrawal of participants is overstated, as only one participant has withdrawn after the previous information release. It would be up to QMUL to explain to participants that their data has been anonymised so that they could not be identified from it so as to allay fears *that* they themselves seem to be attempting to stoke up. Any limited risk of prejudice is considerably outweighed by the public interest in disclosure to assist in the legitimate academic debate. Professor Chalder accepted that there is a public interest in releasing trial data, and that "rational sceptics" receiving the data may assist the academic debate.

20. DECISION:

Taking the issues identified at 5 above we find as follows:

a) Section 22A and the question as to whether or not an exemption should be applied retrospectively? As indicated, and for the reasons given above we agree with and adopt the Commissioner's assertions and reasoning. On considering all the evidence before us, we find there are no

exceptional circumstances whereby the Commissioner ought to have exercised his discretion to apply Section 22A retrospectively on the facts before us. We find the Commissioner was correct in his decision in this respect.

b) It seems to us that the key issue in dispute in this Appeal is on the issue of Personal Data and whether individuals can be identified from disclosure of the disputed information. The test is whether there is a risk that such disclosure would lead to identification of an individual that is more than remote. The Tribunal cannot come to a unanimous decision on this key issue and now set out the reasons for majority and minority decisions.

The Majority decision:

The Commissioner accepts that the question turns on whether anonymization is possible, and he argues that in this instance identification is an extremely remote possibility. Professor Anderson accepted that the information alone cannot identify participants, and his hypothesis that identification is possible through combining that information with NHS data (involving an NHS employee both having breached their professional, legal and ethical obligations and also having the skill and inclination to so do) is implausible:

In short, we accept and adopt the Commissioner's wider submissions and reasoning as set out in his Skeleton Arguments and Written Closing on this issue. In all the circumstances and on the evidence before us we are satisfied that the risk of identification has been anonymised to the extent that the risk of identification is remote. In coming to this conclusion we have also taken into account:

(i) The nature of the information, which did not contain any fixed or direct identifiers

(ii) The evidence of Dr. Rawle that the anonymisation methodology followed the guidelines at the time and would still comply with current guidelines although they were said to be under review for the future;

(iii) The evidence of Dr. Rawle that none of the identifiers were contained in the disputed information, (the anthropometry measures issues was cleared up);

(iv) The evidence of Professor Anderson that third parties could not identify participants from the information alone and that, when pressed, he said that the chance of an "activist" being able to discover information that would lead to individual identification was remote. It was clear that his assessment of activist behaviour was, in our view, grossly exaggerated and the only actual evidence was that an individual at a seminar had heckled Professor Chalder. The identity of those questioning the research, who had signed an open letter or supported it, was impressive. Whilst we accept that Professor Anderson was an expert witness, he was not a Tribunal appointed independent witness but appointed by the Appellant and clearly, in our view, had some self-interest, exaggerated his evidence and did not seem to us to be entirely impartial. What we got from him was a considerable amount of supposition and speculation with no actual evidence to support his assertions or counter the Respondents arguments;

(v) That even on Professor Anderson's evidence for identification to take place there would have to be a breach of medical ethics and the law and there was absolutely no evidence to quantify the risk of this occurring in the circumstances and on the facts before us in this appeal. In fact there was no tangible evidence of an example where such steps had led to identification of an individual in any circumstances.

(vi) That even on Professor Anderson's evidence it was only the walking scores that were likely to lead to identification (if all of his other suppositions and speculation came about);

(vii) That the Fine research had been released, albeit by accident, and there was no evidence that although it contained similar data, that there had been any individual identification or problems arising from it.

(viii) We do not accept the commercial interest arguments of the College. There was very little evidence of the withdrawal of consent and where it had happened it was not directly related to the issues before us. Funding had been obtained for a new trial in the knowledge that this Tribunal may not allow the Appeal. New confidentiality guarantees, or perhaps more explicit ones, could be given to new participants.

(ix) In any event there is a strong public interest in releasing the data given the continued academic interest so long after the research was published and the seeming reluctance for Queen Mary University to engage with other academics they thought were seeking to challenge their findings (evidence of Professor Chalder).

(x) There is insufficient evidence before to persuade us that disclosure of the disputed information would cause sufficient prejudice to QMUL's research programmes, reputation and funding streams.

(xi) Professor Anderson when cross-examined as to whether or not the patient identities (HESID) that were disclosed to anyone with access were encrypted. He was unaware but has since checked and has now confirmed through submissions on behalf of the Appellant that the identities are in fact encrypted. He has not been questioned further on the effect of this but it is submitted on behalf of the Appellant that this does not affect the wider point he made about care data disclosures, that they would potentially allow different health events to be linked where it could be established they related to the same patient identifier. This, we would have

preferred to explore further in evidence but it seems to us that encryption makes the chance of identification even more remote in any event and strengthens our view that the speculative assertions of the occurrence of possible events actually taking place in a way that could lead to identification of individuals, by Professor Anderson are indeed remote.

(xii) We do not accept the speculation that the chance that a determined person with specialist skills could make the link, while less than probable, is more than remote. There is no tangible evidence before us to persuade us that it is less than remote. Professor Anderson accepted it would be extremely difficult to identify individuals even from the collective information, which, as the Commissioner submits "given his approach to this should indicate the near-impossibility of reidentification". We are not persuaded the risk of identification is more than remote.

(xiii) Generally, regarding the Commissioner's discretion, we heard nothing, and are not persuaded on the evidence before us, that would lead us to question that the Commissioner had not applied himself correctly, that his decision was not properly arrived at or should be set aside.

The minority Decision – (Mr Watson dissenting):

a) Each row in the spreadsheet is unique and refers to one person in the trial.

b) The information necessary to link this data to an individual is available to a large number of people due to the way security has been implemented in the NHS and the quantity and nature of information that is now available on social media.

c) I believe Professor Anderson is correct when he gave evidence that the chance that a determined person with specialist skills could make the link, while less than probable, is more than remote.

d) For this reason the information contained in the spreadsheet is personal data and should not be disclosed.

Finally at Paragraph 5 c) above: "*Would disclosure cause sufficient prejudice to QMUL's research programmes, reputation and funding streams to refuse disclosure?*"

We unanimously accept and adopt the Commissioner's wider submissions and reasoning as set out in his Skeleton Arguments and Written Closing on this issue. In all the circumstances and on the evidence before us we are satisfied that the perceived risk of prejudice as submitted by the Appellant's has not been substantiated or demonstrated in evidence before us. Such minimum risk as has been expressed would not in our view outweigh the public interest in disclosure of the disputed information as defined in the specific request in this appeal.

21. The Tribunal wish to thank all parties for the helpful manner in which they have presented their arguments and submissions. We have been provided with an extraordinary amount of ancillary and background information on and about the important subject matter under consideration and have considered all of it. There can be no doubt about the Public Interest in the subject matter which is evident throughout the course of this appeal, and beyond, and we are grateful for the assistance that has been given to us in this regard.

We have considered all of the above arguments, submissions and evidence together with the significant volume of supporting literature and legal precedents and for the reasons given above we refuse the appeal by a majority decision for the above reasons, and the Commissioner's DN stands.

Brian Kennedy QC 11th August 2016.

Promulgated 12th August 2016

AUTHORITIES CONSIDERED

1. *Coco v Clark* – three elements for a cause of action for breach of confidence: a) information of a confidential nature; b) communicated in circumstances importing an obligation of confidence; and c) that there was an unauthorised use of that information.

2. *Ex p Source Informatics Ltd* – a patient has no right to control the way their information is used provided only that their privacy is not put at risk, and where the identity is protected it is not a breach of confidence to disclose it to a third party without the patient's consent.

3. *Derry City Council v ICO* – in the absence of evidence of any likely prejudice that could be suffered as a result of disclosure, it is not possible to conclude that commercial interests would be likely to be prejudiced by disclosure. When considering whether the public interest outweighs any potential prejudice, the categories of public interest are not precisely defined nor necessarily exceptional. The starting assumption is that confidentiality should be maintained unless outweighed by countervailing factors.

4. *ICO v HMRC & Gaskell* – situations may arise where a public authority should have communicated the information at the time of the request, but by the time of the Commissioner's consideration, circumstances have changed such that disclosure has become unlawful, impossible or wholly impractical e.g. the information may have been inadvertently destroyed, disclosure has in the interim become a contempt of court or a new statutory bar has been enacted by Parliament.

5. *APPGER v ICO and MoD* – anonymised data remains personal data only insofar as the un-anonymised data remains with the data controller. Should the anonymised data be disclosed outwith the hands of that data controller it is no longer deemed personal. Disclosure of fully anonymised data is not a breach of DPA.

6. *Dept. of Health v ICO* – statistical data including information as to different foetal abnormalities and the total number of terminations was withheld on the grounds that detailed statistics could, given the small numbers involved in some categories, risk identification of patients or doctors. This argument was rejected, the Court deciding that the risk of identification was extremely remote, therefore Art.8 was **not** engaged and disclosure was ordered.

7. *Spread Trustee Co Ltd v Hutcheson et al* – para.65 confirms the principle of non-retrospectivity unless contrary intention is demonstrated. At paras. 74 and 79 the Court acknowledged that it seems unfair that non-retrospectivity could be seen to protect individuals who have done wrong, but nevertheless affirmed that contrary intention in statute, not fairness, is the question to be answered.

8. *Montague v ICO and Tate Gallery* - para.27 stated that public authorities *obtain* confidential information in the course of performing their functions, but s41 exemption is not intended to apply where the authority makes an agreement simply that the information is confidential i.e. s41 cannot apply simply by reason of the information being stated in the agreement. It is instead intended for protection of existing confidential information held by a third party but which comes into the possession of the authority. Para.32 highlights that individuals providing information to public authorities must be aware that they are dealing with a body subject to FOIA.

9. *Home Office v ICO and Ian Cobain* - the Tribunal found that the words "relates to" only required the public authority to show some connection between the information and the security body. "Relates to" should not be equated with "refers to" which was a narrower concept. Furthermore, the wording of the section distinguished between the origins of the information (its "supply") and its content (what it "relates to"). Section 23(1) must therefore be given a broad but purposive interpretation, subject to a remoteness test. The qualification of remoteness required that the connection between the information and the security body was

"significant" and was necessary because "there are clearly limits to be imposed by common sense and, in a particular case, the probable ambit in principle of the need for protection. Whether information was "supplied" by a security body was a question of fact as to the origins of the information; whether information "related to" a security body was a question of fact to be determined by reference to the contents of the information; and whether information fell within the scope of an exemption was to be determined on the balance of probabilities rather than certainty.

10. *ICO v Colenso-Dunne* - The DPA distinguished between "personal data" and the sub-species of "sensitive personal data but not in terms of potential outcomes or consequences as between different sub-categories of sensitive personal data. Risk of reputational damage must be balanced against the public interest in disclosure where questions have been raised about the propriety of the conduct of the individuals or bodies in question.

11. *Google Inc v Vidal-Hall et al and ICO* – breach of confidentiality is not the same as an infringement of Art.8 privacy rights. Misuse of private information can be characterised as a tort for the purposes of service outside the jurisdiction, but this does not create a new cause of action but rather clarifies the legal label of the wrong that already exists.

12. *I v Finland* - I did not have to show a wilful publishing of data. A failure to keep it secure was enough to breach her Article 8 right. "It is plain that had the hospital provided a greater control over access to health records ... the applicant would have been placed in a less disadvantaged position before the domestic courts," the Court ruled. It went on to find that the Finnish courts' requirement to prove that her record had been misused was "to overlook the acknowledged deficiencies in the hospital's record keeping at the material time."

13. *Polyukhovich v Commonwealth of Australia* – there are no prohibitions on retrospectivity of statutory provisions, even criminal ones, in the Australian constitution. This case referred to bringing those involved in war crimes

since 1939 to justice within the Australian legal system, and so was by necessary implication intended to act retrospectively.

14. *GMC v Savery et al* - The Court held that "the existence of an investigatory procedure and its effective implementation are fundamental to maintaining the confidence of the public in the dental profession." Each disclosure of patient records in non-anonymised form would involve an interference with the patient's right of respect for his private life under Article 8(1). Such disclosures therefore were required to be justified under Article 8(2). Sales J commented that '....the public interest in effective disciplinary procedures for the investigation and eradication of medical malpractice will "invariably" outweigh patient confidentiality save in "exceptional cases"'. Sales J found that the proposed disclosure pursued legitimate objectives set out in Article 8(2), as being "in the interests of ... public safety", "for the protection of health and morals" and "for the protection of the rights and freedoms of others." Particular emphasis is placed in the judgment on the role of the GDC in maintaining public confidence in health services. He made clear that: (a) the disclosure sought was in accordance with the statutory regime in the Dentists Act; (b) all those concerned would be aware of the need to respect the patient's confidentiality; (c) the common law obligation of confidentiality and the possibility of an action for breach of that obligation where there was unjustified disclosure remained; and finally, (d) the obligations in the DPA on those who received copies. Sales J stated *obiter* that "it is arguable that the good practice ... that in ordinary circumstances the person whose confidential information is in issue should be informed that it is proposed to disclose that information to a professional or regulatory body ... will be required under Article 8."