



IN THE FIRST-TIER TRIBUNAL

Case No. **Appeal No. EA/2012/0229**

GENERAL REGULATORY CHAMBER INFORMATION RIGHTS

ON APPEAL FROM Information Commissioner's Decision Notice No: FS50451416

Dated 26<sup>th</sup> September 2012

BETWEEN

Queen Mary University of London

Appellant

And

The Information Commissioner

Respondent

And

Mr Robert Courtney

Second Respondent

Determined on the papers on 26<sup>th</sup> April 2013 at Field House

Date of Decision 22<sup>nd</sup> May 2013

BEFORE

Fiona Henderson (Judge)

John Randall

And

Dave Sivers

Subject matter: FOIA– s22 (Information intended for future publication)

**Decision: The Appeal is allowed.**

### **REASONS FOR DECISION**

#### Introduction

1. This appeal is against the Information Commissioner's Decision FS50451416, dated 26<sup>th</sup> September 2012 which concluded that whilst s22 FOIA was engaged the public interest lay in disclosing the withheld information.

2. The withheld information relates to the “PACE trial” run by Queen Mary, University of London (the University) between 2005 and 2010. This was the largest randomised controlled trial to examine the efficacy and safety of the currently used main clinical interventions<sup>1</sup> for Chronic Fatigue Syndrome/Myalgic Encephalopathy (CFS/ME). The trial was funded by the Medical Research Council and cost approximately £5million and involved 641 patients and several hundred clinicians and researchers.

### The Information Request

3. On 29<sup>th</sup> March 2012 Mr Courtney wrote to the University asking for:

*“Comparison of adaptive pacing therapy, cognitive behaviour therapy, graded exercise therapy, and specialist medical care for chronic fatigue syndrome (PACE): a randomised trial.*

*I would like the “deterioration rates” for each of the therapy groups (CBT, GET, APT, SME) for both the primary measures (Chalder fatigue and SF-36 Physical Function).*

*Specifically, I would like the proportion of participants in each therapy group who deteriorated by 2 or more for Chalder fatigue, and by 8 points or more for SF-36 Physical Function”.*

4. The University initially denied holding the information but following an internal review confirmed that it held the information but that they were relying upon s22 FOIA (Information intended for future publication).

### The Appeal

5. The University appealed against the Commissioner’s decision on the grounds that the balance of public interest lay in withholding the information because publication under FOIA:

- Represented the loss of opportunity to publish,
- Would cause harm to publicly funded research,

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<sup>1</sup> Adaptive pacing therapy (APT), cognitive behaviour therapy (CBT) graded exercise therapy (GET) when added to specialist medical care (SMC) and SMC alone.

- Would harm academic freedom,
  - Would limit the full and adequate dissemination of the conclusions of the project.
6. The Commissioner initially resisted the appeal, relying upon the reasoning as set out in his decision notice. Mr Courtney was joined as a party. The University provided a detailed Reply dated 29<sup>th</sup> November 2012 in which they clarified certain factual issues and expanded upon their public interest arguments. They also submitted a witness statement from Professor White the Lead Co-Principal Investigator of the PACE trial and supporting exhibits. Following the submission of this evidence and notwithstanding the detailed representations made by Mr Courtney the Commissioner notified the Tribunal and other parties on 18<sup>th</sup> December 2012 that he now accepted that the public interest in maintaining the exemption in this case outweighed the public interest in disclosure.

#### Scope of the Appeal

7. In his response to the University's submission and evidence Mr Courtney has sought to clarify his request as follows:

*“The FOI request was in relation to the PACE Trial paper, published in 2011, and does not relate to any related papers that have been published, or will be published in the future. As such the deterioration rates are required at 52 weeks, the same time frame for the “improvement rates” (Number improved from baseline) that were published in the original paper in 2011.”*

The Tribunal notes that it would not be possible to change the terms of the request now as its jurisdiction is in relation to consideration of the information that falls within the ambit of the original request, however, necessarily that must relate to the information which was held and identified at the time of the original request.

8. Mr Courtney does not dispute that the disputed information is held with a view to publication and therefore that it falls within the remit of section 22 FOIA. The only issues to be decided by the Tribunal are therefore whether,
- a) in all the circumstances of this particular case, it is reasonable for the information to be withheld until the date of intended publication and

b) whether the public interest in maintaining the exemption outweighs the public interest in disclosure.

9. We accept the Commissioner's contention that since the intention is to release the data, the Tribunal must concern itself with harm that might arise from early disclosure ahead of the scheduled release date. The Tribunal would also add to this harm arising out of the context in which information is disclosed.

Factual assumptions in the Commissioners reasoning in the decision notice

10. In his Decision Notice the Commissioner weighed up the public interest upon the basis that a paper had been published in 2005 and that the published information only included positive outcomes. The inference drawn was that the data had been available since 2005 and there had already been a seven year wait for the complete data.

11. The University challenged this as factually inaccurate and provided evidence from Professor White that:

i) the trial was not complete until 2010 and that the full research publication strategy has involved the statistical analysis of many thousands of data fields and thousands of hours of researcher and statistician time in analysis, paper drafting, editing and revision, all undertaken since trial completion in 2010.

ii) The March 2011 Paper which provoked the information request was a peer reviewed paper<sup>2</sup> in the Lancet which set out the main safety and efficacy findings from the PACE trial concluded that CBT and GET can safely be added to SMC to moderately improve outcomes if treatment is provided and supervised by appropriately trained and qualified therapists. These findings were based on both the positive outcomes and the safety data<sup>3</sup>.

12. We accept this evidence as to timing and also as to the fact that some deterioration data has been published (although not the specific data requested by Mr Courtney)

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<sup>2</sup>Other scholars who volunteer their time evaluate the work and then write a review and recommendation for the publisher and feedback comments for the author. The review can include the research method, validity of statistics and conclusions.

<sup>3</sup> 6 distinct measures of safety and deterioration including use of the same measure (SF36 physical function subscale) as requested by Mr Courtney.

and are satisfied that the Commissioner's decision was influenced by a material error of fact.

Reasonableness of withholding disclosure until the intended publication date.

13. The evidence before the Tribunal is that it is intended that the information be published in a peer reviewed paper. The main paper (which triggered this request) was published in March 2011, in 2012 another primary paper was published and 3 other papers will be published in 2013 including that with the requested data. The papers published thus far are all peer reviewed and openly available. It is not therefore possible to give an exact date as that depends upon the publication schedules of individual publications and the time taken by the peer group to review the work (it can take at least 90 days) and any comments they may have upon its content when thus reviewed. It is not normal to make concurrent submissions to different journals, so in the event that an article is rejected the process has to start again with another publication.
14. Mr Courtney's concern is that the University might change its mind and the data will never be published. All that is necessary for s22 to be engaged is for the public authority to have the "intention" to publish it at a future date. We are so satisfied. The Tribunal notes the stage at which the process had reached by the time the evidence was submitted in this case (namely revised due to internal review and almost ready for submission to a journal) and the evidence from the Editor of a journal confirming that the University were intending to submit the data to them as part of an article. In light of the scale of the project and the clear evidence of a structure and timetable to the analysis of the data and the publication of the conclusions from this analysis, we are satisfied that the timescale is reasonable, and that subject to consideration of the public interest as set out below it is reasonable to withhold the information until the date of publication.

In favour of withholding disclosure

15. The Tribunal was referred to the Research Councils UK Common Principles on data policy which states:

*“To ensure that research teams get appropriate recognition for the effort involved in collecting and analysing data, those who undertake Research Council funded work may be entitled to a limited period of privileged use of the data they have collected to enable them to publish the results of their research. The length of this period varies by research discipline and, where appropriate, is discussed further in the published policies of individual Research Councils.”*

16. The Medical Research Council (who funded this project) state in their policy that:  
*“A limited, defined period of exclusive use of data for primary research is reasonable according to the nature and value of the data and how they are generated and used. Ongoing research contributing to the completion of datasets must not be compromised by premature or opportunistic sharing and analysis. Sharing should always take account of enhancing the long-term value of the data”.*
17. The University argue that having undertaken the work to collect the raw data they should have the opportunity to present it in the context of complete and appropriate scientific commentary which has been tested by peer review. They argue that peer review is a fundamental of academic good practice and is recognised as part of the UK’s evaluation and funding of high quality research. Premature publication of provisional research results particularly if made in a lower ranking journal might undermine the credibility of the final conclusions. Without peer review they argue that they would be casting clinicians and patients adrift with a great deal of information from which they will have to make uninformed decisions, as the data would lack sufficiently rigorous contextualized commentary and could be manipulated to appear to support pseudo scientific findings and claims.
18. Mr Courtney has drawn our attention to the fact that even the peer reviewed article in Lancet in March 2011 appears to have been misinterpreted e.g. in the way it has been reported in the press. We also note that there is nothing to prevent misinterpretation or improper manipulation of the raw data after publication in an article.
19. The Tribunal has considered whether the risks associated with the release of raw data can be met through the University releasing explanatory commentary simultaneously with data disclosed pursuant to a FOIA request. However, we accept that disclosure of this commentary would be “too early” in that it would be in the absence of

appropriate peer review which includes discussion of its strengths and limitations and validates the work done prior to publication. This would lower the dependability of the work done and thus devalue the work already done. We also note the University's concern that in the absence of publication in a well regarded peer reviewed journal they would be limiting the full and adequate dissemination of their conclusions and that as a lone voice without the validation of peer review they would be in a weaker position to challenge pseudo scientific findings and claims based upon misinterpretation of the raw data.

20. We are satisfied that value for money already invested comes from contextualization of scientific data. Without peer review of the way it has been assembled and validation of the analysis and scientific commentary, the work already done will lose value .
21. Mr Courtney argues that the desire of certain journals to have exclusive rights to the publication of articles is a private commercial concern and not material to the balance of the public interest. He argues that there is nothing to stop the University using the same data in a peer reviewed article after the raw data has already been released, he cites disclosures of data at scientific symposia prior to article publication. The University dispute that this would be feasible and rely upon a letter from Dr. Levenson, the North American Editor of the Journal of Psychosomatic Research, a peer reviewed journal who states:

*“the pre-publication of important data or analyzed results from a research study or trial [outside the setting of a scientific conference with no scientific commentary] could have a prejudicial effect on my decision to consider the paper for publication that includes such data or results”.*

21. We accept the distinction between disclosure to the world at large with no scientific contextualization and disclosure with scientific commentary to a peer group albeit in a public or semi public forum. We also note the terms of the sample declaration of authorship form to a journal which requires the authors to certify that the work reported in the paper has not been and is not intended to be published anywhere except in [the named journal]. We are satisfied that prior publication of raw data under FOIA could jeopardize the opportunities for the same data to be published in a peer reviewed journal, and as such would not enhance the long term value of the data.

We do note that once the data has been made public in a journal it is then available for the use of others.

22. To the extent that the University's argument includes an assertion that disclosure under FOIA would impinge upon academic freedom and that those collecting the data should have academic freedom to choose what to publish, where and when for reasons of academic prestige regardless of the public interest; where the research has been conducted with the use of public funds, we reject this. We consider academic freedom to relate to the freedom to pursue research wherever the evidence takes a researcher and the freedom to disseminate, publish and teach no matter how unpopular and controversial the conclusions. That academic freedom must be viewed in the context of the public interest is clear from the structure of s22 FOIA which is subject to the public interest test.

#### In favour of disclosure

23. The Medical Research Council (quoting OECD *Promoting Access to Public Research Data for Scientific, Economic and Social Development*) states that publicly-funded research data are a public good, produced in the public interest and that they should be openly available to the maximum extent possible.
24. We also accept that sharing of data can be used to increase the return on public investments in scientific research, through the exchange of good practice, and preventing duplication of effort and maximizing the academic and scientific scrutiny of data.
25. MRC policy does not prescribe when or how researchers should preserve and share data but requires them to make clear provision for doing so when planning and executing research. Such data must be shared in a timely and responsible manner.
26. We note that Mr Courtney's information request came 1 year after the March 2011 paper and that in timing his request thus he has allowed for a defined period of exclusive use of data for those that gathered it. He argues however, that it is taking too long for the complete data to be made public.



27. He relies upon the MRC statement that “at the end of 2012, we made both the requirement to publish, and the need for MRC-funded researchers to share data, even more explicit: *“results of MRC-funded clinical studies (whether positive or negative) must be published within a reasonable period (generally within a year of completion) following the conclusion of the study”*.”<sup>4</sup>
28. We do not consider that it would be fair to apply the current MRC definition of reasonable (“generally within a year of completion”) to this study since this study (the planning for which would have included the timetabling of the analysis and publication of the data) predates the 2012 guidance. As set out above we accept that clear provision has been made for the analysis and publication of the data and that the explanation for the timing of this is reasonable.
29. Mr Courtney argues that withholding the disputed information is cherry picking the information upon which the scientific community and patient groups can comment. It is creating a one sided debate and is preventing those who would wish to scrutinize or challenge the results from completing their analysis of the data. He argues that the March 2011 paper was not comparing like with like and presented a misleading picture because the harm data used had a 20 point difference, whereas the improvement data was assessed on an 8 point difference.
30. He points to the fact that the results and analysis as set out in the March 2011 paper have already been incorporated into the interim review of the NICE CFS/ME guidelines to support the NICE recommendation for CBT and GET. He argues that clinicians and patients are being required to embark on treatments without the ability to assess risk of deterioration before choosing a treatment. Without the disputed information the evidence behind the regulator’s decision cannot be independently assessed.
31. The University argue that disclosure of the raw data without sufficiently robust scientific contextualization will not assist clinicians or patients to make proper use of the information and would be likely to lead to misinformation and confusion. They

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<sup>4</sup> Alltrials website.

further argue that disclosure of the data will not materially alter the conclusions they have reached as already set out in the March 2011 paper. The Tribunal is not in a position to make a determination as to what extent that is accurate but observes that there is often room for debate in the interpretation of data amongst scientists.

32. We are satisfied that knowing the basis upon which the conclusions in the March 2011 paper have been drawn, does enable the argument to be had as to the reliance that should be placed upon it by e.g. the regulators, in the absence of the full deterioration data. We remind ourselves that we are evaluating the consequences of disclosure now rather than at a date in the near future.
33. Having considered the competing arguments we are satisfied that disclosure under FOIA would not be in the public interest. The additional time sought by the University prior to publication is necessary to enable the proper analysis and scientific commentary to be prepared and then scrutinized through a process of internal review and then external peer review both of which are in the public interest in order to ensure scientific rigour is maintained and that maximum value is achieved from the public investment.

#### Other Matters

34. The burden of showing that an exemption is properly applied rests upon the public authority, and it is unfortunate that the University did not provide sufficient information to the Commissioner to enable them to discharge that burden. Although it might be argued that this was a question of resources, the Tribunal makes the observation that FOIA is a statutory obligation and that in going to appeal it is likely that this has proved to be a false economy.

#### Conclusion

35. For the reasons set out above we are satisfied that the public interest lies in favour of withholding the information and that s22 FOIA has been properly applied. We therefore allow the appeal.

Dated this 22<sup>nd</sup> day of May 2013

Fiona Henderson  
Tribunal Judge