Freedom of Information Act 2000 (FOIA)

Decision notice

Date: 9 January 2013

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

Decision (including any steps ordered)

1. The complainant has requested copies of all meetings of the PACE Trial Steering Committee, Trial Management Group and Data Monitoring Ethics Committee.

2. The Commissioner's decision is that Queen Mary, University of London (QMUL) has correctly applied section 36(2)(b) of the FOIA.

3. The Commissioner does not require the public authority to take any steps.

Request and response

4. On 31 July 2012, the complainant wrote to QMUL and requested information in the following terms:

"I would like to make an FOI request for the meeting minutes of the PACE trial's Trial Steering Committee and Trial Management Groups. I am aware that an identical request was recently made and denied and apologise in advance for making another request for the same information"

5. QMUL responded on 5 September 2012 and referred the complainant to the response it had issued to the earlier request.

6. QMUL declined to carry out an internal review since it had already done so on the earlier request.

Scope of the case

7. The complainant contacted the Commissioner on 6 September 2012 to complain about the way his request for information had been handled. The complainant provided detailed arguments to the Commissioner as to why he felt the minutes of the Trial Steering Committee (TSC) and Trial Management Group (TMG) should be disclosed and provided a number of links to other articles relating to the PACE Trial and treatment of CFS/ME. The Commissioner received the complaint on 6 September 2012.

8. The Commissioner considers the scope of this case to be to determine if QMUL has correctly applied section 36 of the FOIA.

Background

9. The PACE trial was a clinical trial carried out by QMUL commencing in 2002. This PACE (Pacing, graded Activity and Cognitive behaviour therapy: a randomised Evaluation) trial was a large scale trial to test and compare the effectiveness of four of the main treatments available for people suffering from chronic fatigue syndrome (CFS), also known as myalgic encephalomyelitis (ME).

10. Results from the PACE trial have been published in The Lancet and the QMUL website (http://www.pacetrial.org/) provides further information and details of the trial.

11. The Commissioner notes that the PACE trial is controversial and there are some organisations and individuals opposed to the treatment methods used.

Reasons for decision

12. Section 36(2) of the FOIA states that:

"Information to which this section applies is exempt information if, in the reasonable opinion of a qualified person, disclosure of the information -

(b) would, or would likely to inhibit –

(i) the free and frank provision of advice, or
(ii) the free and frank exchange of views for the purposes of deliberation, or

(c) would otherwise prejudice, or would be likely otherwise to prejudice, the effective conduct of public affairs.

13. The exemptions listed in section 36(2) are qualified exemptions so are subject to the public interest test. However, before considering the public interest the Commissioner must first consider whether the exemptions are engaged.

14. For any of the exemptions listed in section 36(2) to apply the qualified person for the public authority must give their reasonable opinion that the exemption is engaged. The qualified person for QMUL is the Principal, Professor Simon Gaskell. QMUL has provided the Commissioner with evidence to demonstrate that the opinion has been sought and provided.

15. The Commissioner is satisfied that Professor Gaskell is a qualified person for QMUL and that his opinion was given at the relevant time. He has gone on to consider whether that opinion was reasonable.

16. QMUL advised that the qualified person is a scientist and researcher with many years' experience, fully familiar with the workings of a medical research project and understood the issues presented in this case to form his own opinion.

17. The Commissioner has been provided with a copy of the submission made to the qualified person, which included information supporting a recommendation.

18. The submission argued that releasing the meeting minutes;

- could have major implications as to how trials are conducted on a national level in future;
- will alter the way in which trials are run;
- will alter the way in which minutes are recorded, particularly in controversial areas of medicine such as this.

19. In addition, QMUL stated that a previous FOIA release of information had already damaged the trial, by delaying the analysis.

20. QMUL has provided sufficient evidence to illustrate that the qualified person was provided with documentation explaining that he was

required to form a reasonable opinion in relation to the application of section 36(2)(b)(i) and 36(2)(b)(ii) of the FOIA to the information withheld by QMUL.

21. In reaching a view on whether the opinion is reasonable the Commissioner will consider the plain meaning of the word 'reasonable' – i.e. whether the opinion is in accordance with reason, not irrational or absurd.

22. The qualified person has stated that in his opinion the disclosure of the requested information *"would undoubtedly inhibit, and arguably endanger, current and future trials".*

23. The Commissioner considers that, given the candid nature of discussions and the expectation of confidentiality from those concerned, it is reasonable for a qualified person to conclude that disclosure of the minutes would inhibit (i) free and frank provision of advice (ii) free and frank exchange of views. The Commissioner is satisfied that the opinion was reasonably arrived at, and he agrees that the exemption is engaged.

24. Section 36(2)(b) is a qualified exemption and therefore it is subject to the public interest test. The Commissioner must consider whether, in all the circumstances of the case, the public interest in maintaining the exemption outweighs the public interest in disclosing the information. As the Commissioner agrees that the exemption is engaged he has gone on to consider the public interest test.

25. QMUL has recognised that there is a public interest in releasing the requested information in that research is publicly funded; it would increase understanding of how the trial was managed and how decisions were made, and its effectiveness.

Public interest arguments in favour of disclosing the requested information

26. QMUL recognised there is a public interest in the disclosure of research that is publicly funded as here, to permit, among other things, the public to monitor the expenditure of public funds.

27. It also recognised that in the conduct of public affairs the public interest in providing a space to think or engage in debate freely to reach a decision that affects the public usually lessens when the decision has been made or the policy reached.

28. There is an important public interest in the transparency/accountability of public authorities and the ability of the public to monitor activities of

public bodies and understand how decisions were taken that affect them.

The complainant's arguments as to why the public interest favours disclosure

29. The complainant argued that there were numerous methodological inconsistencies and/or changes made between PACE's published trial protocol and the analysis reported in the Lancet; all of which were approved by PACE's TSC and/or TMG. Since these changes substantially altered the analysis, interpretation and conclusions drawn from PACE and were either suggested and/or approved by PACE's TSC and/or TMG, it is of substantial public interest to know the content and substance of the deliberations involved in order to determine what justifications and/or rationales were given for making such changes over the course of the trial.

- *Substitution of Outcome Measures*

30. The complainant explained that prior to PACE's publication in the Lancet, the authors substituted both of the trial's primary outcome measures for fatigue and physical functioning which had been established in PACE's published trial protocol several years prior. Changes were also made to the threshold scores which outlined what was needed for a result to be classed as a 'positive outcome'. Numerous other outcome measures were also changed by the authors, who stated that most, but not all, of these changes occurred prior to data analysis

31. The complainant went on to detail further arguments around changes to the trial protocol and provided arguments around what constituted the 'normal range' and its importance to how PACE's results were and continue to be publicized.

32. The complainant provided further information regarding the Chalder Fatigue Scale. The other primary outcome measure listed in PACE's trial protocol, i.e. using the Chalder Fatigue Scale to measure a participant's fatigue, was also changed between the trial protocol and Lancet paper, with many of the above concerns applying to its change as well.

33. The complainant stated that since PACE's TSC and TMG meeting minutes are the only sources of information as to how and why these changes were made, and since these changes had such far reaching impact on PACE's analysis and conclusions, it is of substantial public interest to know the justifications and/or rationales given for making such changes.

The complainant went on to provide further arguments and information relating to;

- *Characterization of PACE's results contradicted by other published research.*
- *PACE's authors dropped one of only two objective outcome measures which were to be included in the trial.*
- *One of only two objective measures of outcome which was to be used in the PACE trial, specifically that of actometer data, was also dropped by the authors.*
- *Descriptions of results reported in PACE contradict previous characterizations by PACE's authors.*

34. Since PACE's TSC and TMG were substantial arbiters regarding how PACE's results were to be analysed and since the authors' characterizations of the outcomes reported in PACE vary considerably at the beginning and end of the trial, it is of substantial public interest to release the meeting minutes of PACE's TSC and TMG in order that these discrepancies can be reconciled.

35. The complainant then stated that another question that arises on the matter comes from the request for Substantial Amendment 5.1 made to the West Midlands Research Ethics Committee dated 20 February 2006. In this request, Peter White, Co-Principle Investigator (PI) of the PACE trial, requested that PACE's entry criteria be raised from a SF-36 PF score of 60 to a 65 in order to increase recruitment.

36. This request includes the following statement: "*The Trial Management Group proposes a substantial amendment to the PACE trial protocol to allow a more representative sample of patients with CFS/ME to be offered the trial. The Trial Steering Committee, at their meeting of 23 January 2006, gave approval of this change to be submitted to the MREC*." As part of the justification given for this request for substantial amendment, Prof. White assured the MREC that:

    "*This would mean the entry criterion on this measure was only 5 points less than the categorical positive outcome of 70 on this scale. We therefore propose an increase of the categorical positive outcome from 70 to 75, reasserting a 10 point score gap between entry criterion and positive outcome. The other advantage of changing to 75 is that it would bring the PACE trial into line with the FINE trial, an MRC funded trial for CFS/ME and the sister study to PACE*."

37. The complainant stated that as noted above, instead of the authors following through with their assurances to the MREC regarding raising the categorical positive outcome from a SF-36 70 to a 75, which would have kept a 10 point gap between PACE's entry criteria and positive

outcome as the authors state, upon PACE's publication in the Lancet the authors instead *decreased* this threshold by 10 points, from the SF-36 score of 70 to the post-hoc 'normal range' SF-36 score of 60.

38. Since there is no record of the authors asking for or receiving approval from the MREC for any subsequent alterations to PACE's entry criteria or positive outcome measure, this means that the West Midlands MREC was given incorrect information in support of making this substantial amendment to PACE, with this request for substantial amendment being done at the behest of PACE's TSC and TMG.

39. It is therefore very much in the public interest to know what justification(s) were given by PACE's TMG and TSC for not following through with the assurances given to the West Midlands MREC in this request since it is questionable whether these requested changes to PACE would have been approved had such assurances not been made.

40. The complainant argued that PACE's sister trial reports no improvements using same outcome measures as PACE originally was to use. The FINE trial, PACE's MRC-funded sister trial on more severely affected patients, used many similar or even identical outcome measures as PACE was originally to use and was first submitted for publication over a year prior to PACE.

41. The FINE trial however did not deviate from these shared outcome measures as PACE did and was widely considered to be a failure upon its publication since FINE reported no significant reductions in fatigue or physical function at its primary end point (70 weeks), instead only reporting a 'clinically modest' reduction in fatigue, again with no improvement in physical function, at the end of treatment (20 weeks).

42. The complainant explained that since the FINE trial was completed over a year prior to PACE's publication in the Lancet and since the two sister trials were so closely tied together, PACE's authors would have been well aware of FINE's results.

43. The complainant stated that there were numerous other changes made between PACE's trial protocol and published Lancet paper. Two examples of such changes are the measures for clinically important and/or useful differences and adverse reactions to treatment.

44. In addition to concern about changes being made from a trial's protocol, the complainant stated that there is also a growing concern in medical research literature regarding the use of 'spin' in the reporting of a RCT results, with a 2012 paper on the subject by Yavchitz et al. stating *"In an ideal world, journal articles, press releases, and news stories would all accurately reflect the results of health research. Unfortunately, the*

findings of randomized controlled trials (RCTs—studies that compare the outcomes of patients randomly assigned to receive alternative interventions), which are the best way to evaluate new treatments, are sometimes distorted in peer-reviewed journals by the use of "spin"—reporting that emphasizes the beneficial effects of the experimental (new) treatment..."Spin" can distort the transposition of research into clinical practice and, when reproduced in the mass media, it can give patients unrealistic expectations about new treatments. It is important, therefore, to know where "spin" occurs and to understand the effects of that "spin"".

45. The complainant considered that the issue of 'spin' in RCT reporting has relevance to the present FOI request due to the fact that PACE's authors were widely quoted in the media and in official trial newsletters as stating that trial participants who met a post-hoc threshold at the end of the trial, which was not part of the trial protocol and which was actually worse than the trial's entry criteria which required 'severe and disabling fatigue', had gotten 'back to normal' as a result of the intervention, with subsequent media reports declaring that these same participants had 'recovered' as a result of the intervention despite potentially no improvement being necessary for a participant to meet this threshold. Furthermore, the criteria for this so-called 'recovery' was fully 25 points lower than the criteria for recovery which had been established in PACE's Trial Protocol (SF-36 85 plus various other outcome measures).

46. The complainant further stated that official press releases for the PACE trial display many of the same problems highlighted by Yavchitz et al, with the press release from the MRC stating *"Two effective treatments benefit up to 60 per cent of patients with Chronic Fatigue Syndrome or Myalgic Encephalomyelitis (CFS/ME), according to a collaborative trial funded by the Medical Research Council (MRC) and UK government departments...The findings suggest these two treatments should be offered to all patients who are able to attend hospital if they are suffering from fatigue caused by CFS/ME."*

47. However the official MRC press release (among others) completely neglected to mention the fact that 45% of the standard medical care control group also reported such improvement, thereby making the assertion that '60% of patients benefitted from the intervention' rather spurious.

48. The complainant argues that the issue of increased transparency is especially pertinent given the fact that many of the discrepancies noted in this appeal are not readily available in the public arena but rather come from documents which were obtained through previous FOI requests. Since the meeting minutes of PACE's TSC and TMG would be the only authoritative source regarding the changes made to PACE's

analysis as well as to how certain outcomes would be reported, it is strongly in the public interest that they be released.

- *QMUL's refusal*

49. The complainant stated that the changes to the PACE trial's analysis described in this appeal are not a comprehensive analysis and therefore not all changes from the trial protocol are covered. However given the overall cost of the PACE trial, the number and significance of the deviations which occurred from the trial protocol, the fact that PACE's authors did not follow widely endorsed guidelines such as CONSORT in reporting the results of their trial as well as the considerable variation in how trial participants who met certain thresholds were characterized by the authors at different points in time, releasing the meeting minutes of PACE's TSC and TMG is very much in the public interest since these minutes are the primary source of information on how the PACE trial was to be analysed.

50. Furthermore, information on many of these changes would not have been available to PACE's peer reviewers since they were not in the public domain at the time of PACE's submission to the Lancet but only became available following FOI requests.

51. It was the complainant's belief that QMUL's refusal to release PACE's TSC and TMG meeting minutes primarily centres around the issue of academic freedom, i.e. the ability of academics to pursue controversial theories without censure. However since PACE's authors are designing, analysing and drawing conclusions from studies costing over £5 million of taxpayer monies (including funding from the Department of Work and Pensions,) and which were published with the stated intent *of "provid[ing] important information about efficacy, adverse events, cost-effectiveness, process and predictors"* in order to *"inform patients, their carers, healthcare providers and commissioners which treatments are most useful for which patients, and provide information regarding the essential process of both recovery and improvement from CFS/ME*", he suggested that the bar for exemptions from public interest tests should be set much higher in this instance since patients' care is being directly impacted as a result.

52. The complainant has also picked up on QMUL's refusal notice it which it notes that "it is also recognised that in the conduct of public affairs the public interest in providing a space to think or engage in debate freely to reach a decision that affects the public usually lessens when the decision has been made or the policy reached."

53. Seeing as how the substantial majority of QMUL's refusal is based on this issue combined with the fact that the results of the PACE trial were

published in early 2011, what is now being requested is an increase in transparency so that these decisions (which have already been reached as QMUL notes) can be subjected to entirely appropriate and necessary scrutiny which can then serve to improve the quality of any future decisions and/or decision making processes.

54. The freedom to put forward controversial and/or unpopular ideas should also not be used as an excuse from having the decisions surrounding costly and time-consuming research studies being subjected to entirely appropriate and necessary scrutiny, especially when a study's outcomes directly affect a vulnerable group of patients. Furthermore, as stated above, this request does not simply involve 'unpopular ideas or opinions', rather what is being requested here is an increase in transparency regarding the substantial deviations in the design, analysis and conclusions in the PACE trial which resulted in what appears to be a contradictory and/or inconsistent analysis of the study's results.

55. Given the overall size and cost of the trial, the fact that the trial was funded entirely on public funds as well as the authors' stated intent of influencing healthcare provision with the results, the PACE trial has the potential to affect millions of patients around the world which makes the issues enumerated in this request very much in the public interest.

56. Given the fact that the £5 million+ spent on the PACE trial dwarfed MRC expenditures on ME/CFS for the entire previous decade, with no less than 37 other research projects being rejected during this approximate timeframe the complainant considers that the substantial public interest inherent in the PACE trial outweighs the interests QMUL cites for keeping the meeting minutes private.

Public interest arguments in favour of maintaining the exemption

57. QMUL stated that faculty members including scientific researchers often share their thoughts and views with one another. This is especially true where the scientific examination of an issue is a collaboration among scientific researchers such as with the examination of treatment outcomes in the PACE clinical trials.

58. It is further true that in the instant case the requested minutes reflect the opinions/exchanges of the principal investigators and other members of the research team on a range of issues regarding the structure, proper conduct and ongoing evaluation of the trials. The confidentiality of such discussion and debate can be vital to the development of scholarship, knowledge, and scientific truth which is the public mission of QMUL.

59. Faculty members and other researchers and individuals with whom they collaborate in these endeavours must be afforded privacy in their exchanges in order to pursue knowledge and develop lines of argument and scientific findings without fear of reprisal for findings or ideas that are controversial and without the premature disclosure of those ideas.

60. QMUL further argued that it was also reasonable to conclude that disclosure would inhibit the quality and freedom of future exchanges among academic researchers who continue in the field and to recruit important participants outside academe to get involved in the studies.

61. A review of the minutes in question reveals sensitivity among the researchers in light of the highly politicised and polemic nature of elements of the public debate noted above. In this environment, researchers fully expected the meetings to be closed to the public and the minutes to be confidential.

62. These responses express strong views as to the negative impact on future exchanges and the willingness of some important participants to be involved, for example, patient representatives whose role is to help ensure a public oversight and balance of views and who would not participate if their identities or view/statements as reflected in the minutes were disclosed to the public.

63. Furthermore, QMUL stated that there are other studies planned and beginning and disclosure of the identity/opinions of the participants in the completed study could likely impact participation and exchange of views and analysis on other studies. Since ME/CFS is an area where there is a significant need for ongoing research, the public interest in continuing to perform such studies in an atmosphere conducive to academic freedom is great with the potential prejudice to its quality and successful completion real and significant.

64. QMUL explained that the research and its findings have been fully and timely published in a respected peer reviewed journal, The Lancet, with access to the findings fully available to the public.

65. Moreover, these findings have been subject to extraordinary public scrutiny. The Lancet, in response to extensive public commentary, in an unusual procedure, subjected the study to a further peer review process.

66. QMUL also stated that while the requestor here suggests that the minutes would be helpful to provide the public information as to the findings in light of investigator's conflict of interests these interests were disclosed with the published study. It is not viewed that the minutes in

question would further the public interest by providing more information in this regard to the public.

67. In addition, QMUL stated that in this case, there is an ongoing scientific process, both with new studies, one of which is advised as to be just underway and another planned longitudinal evaluation of data from the study in question. There is, therefore, a continuing need to protect the free and frank exchange of views in such ongoing studies and to promote the public interest in protecting academic freedom and the College's future effective conduct of its public affairs mission to engage the effective conduct and evaluation of scientific knowledge here without fear of public reprisal.

68. QMUL has also provided copy correspondence from a patient representative group.

69. This letter states that it was an active and full member of the TMG and observers of the TSC. It believed that this was important in influencing trial design and implementation to the benefit of patients and their carers'.

70. It was of the view that releasing the requested information would be prejudicial to the conduct of such committees in current and future studies and trials of treatment of CFS/ME.

71. It further stated that it was essential that patient/member organisations such as theirs are able to participate in such committees and have discussions that are not inhibited in any way. Knowledge that minutes may be released in this way will have a negative effect on its further decisions to participate in future committees.

72. Furthermore, it stated that if it had known that minutes were likely to be published it would not have committed itself to participate in the way it did. It believed that this was even more the case for individual patient representatives.

73. Finally, it stated that it was essential that a range of stakeholders and patient organisations are supported to engage in groups such as these without fear of public recrimination or condemnation. It believed that releasing the requested information would likely damage future studies and trials by inhibiting participation by patient representatives and patient organisations.

74. During the internal review process further consideration was given by QMUL to the public interest.

75. The internal review of the trial minutes, manuals, trial protocol, the Lancet publications, the interview statements and other material

indicated that, in contrast to the complainant's suggestion, the PACE trial was not related to a debate about psychiatric understanding versus biomedical.

76. The trial was intended and designed to test treatments currently available within the NHS that were based in reversing maintaining factors in the illness, not causative factors *per se*, which were a mixture of physical (e.g. deconditioning) and psychological (e.g. coping behaviours) factors. The review indicated that the statement of the Trial Senior Statistician concurred and indicated no scientific justification existed for disclosing the minutes.

77. QMUL explained that attempting to evaluate if there was proper balancing of the complainant's public interest rationale of determining suggested collusion, predetermined results, conflicts of interests and lack of scientific rigour as requiring the minutes' disclosure, the internal review of the trial management group indicated that it contained more physicians than psychiatrists.

78. A review of the background literature on CFS/ME indicated that medical authorities, including investigators, do not regard the illness as purely psychological in its nature, but as both physical and psychological.

79. Similar claims of collusion between government, researchers and the insurance industry regarding disability-related benefits or insurance payments with respect to a number of the trial researchers involved in the PACE trial were found to have been previously reviewed in another context but found wanting previously as indicated by the decision in *R (on the application of Fraser and another) v Nat'l Inst for Health and Clinical Excellence and another* [2009] EWHC Admin (452) including the unusual Afterword, by Simon J.

80. As part of this further evaluation, the QMUL staff member reviewed The Lancet 2011 trial outcomes article and The Lancet process. This found that The Lancet not only published the main results of the PACE trial in a 2011 article that was initially peer-reviewed by several referees, but also in response to the referenced criticisms cited by the complainant, had apparently conducted a second evaluation.

81. QMUL explained that The Lancet is known to the academic medical community as a highly respected journal. Research metrics show that it is the second most highly cited medical journal in the world. Not only did this dual peer review take place, in another unusual accompanying editorial The Lancet addressed considerations similar to those raised as contributing to the public interest by the requestor here. The journal stated: *"White and colleagues have been accused of having "formed their opinion about the intended outcome" before the trial began. This*

view is unjustified and unfair. The researchers should be praised for their willingness to test competing ideas and interventions in a randomised trial. The evidence might even suggest that it is the critics of the PACE trial who have formed their opinions first, ignoring the findings of this rigorously conducted work" (The Lancet, 2011).

82. After having reviewed all of the above, the staff member prepared a report for the Principal entitled 'Analysis for Qualified Person's consideration on internal review'. This was provided to the Principal for his further opinion as to whether the exemption should be maintained on 2nd July 2012. On 11th July 2012, the Principal determined that the opinion to maintain the exemption should stand.

83. QMUL stated that independent advice had been sought and given in many areas in connection with the Trial by the TSC. This included, for example, issues of patient safety, trial implementation, and review of the clinical interventions used. These advisers must be free to give their opinions based on their expertise and which must be fully minuted in order to document and be able to re-examine why decisions were made in the course of a long-term study.

84. QMUL considered that publication of the requested information where this advice is reflected would prejudice the provision of full and frank advice in light of hostility and public reprisal that these advisers would likely to be subject to from a small, but notable part of the CFS/ME activist patient community.

Balance of the public interest arguments

85. In finding that the above exemption is engaged, the Commissioner has already accepted that the disclosure of this information is likely to result in the inhibition set out in the exemption. However, in considering the balance of the public interest, the Commissioner takes into account the severity, frequency, or extent of any inhibition that would or might occur. He has considered the nature and content of the withheld information and the timing of the request.

86. The withheld information consists of minutes of meetings of the TSC and TMG. The Commissioner has examined these and has ascertained that they related to a number of issues, for example, the structure of the clinical trial. The information contains a number of views and opinions expressed in those meetings; details a number of options explored and actions to be taken.

87. The Commissioner understands that these meetings have now ceased as the trial has been completed and the results published.

88. The Commissioner considers that participants of such meetings need time and space for free and frank discussions regarding the best and most appropriate way to conduct clinical trials, provide advice and decide upon options to take.

89. The Commissioner considers that there is a strong public interest in openness, transparency and accountability in the decision making processes of public authorities. He also considers that there is a strong public interest in allowing the public to be better informed about the way clinical trials are conducted.

90. The Commissioner also acknowledges the strength of feeling and time spent by the complainant compiling his arguments, and others concerned with the treatment of CFS/ME. The Commissioner has fully considered all the arguments raised by the complainant although these are not all detailed in this decision notice.

91. The Commissioner has considered the severity, extent and likely frequency of inhibition to the provision of advice and the free and frank exchange of views for the purposes of deliberation which disclosure of the withheld information would be likely to pose. He is satisfied that QMUL is entitled to protect a safe space for discussion about the implementation and set up of clinical trials, particularly when further trials are ongoing and planned for the future.

92. Given the nature of the withheld information, the Commissioner considers that significant prejudice would be likely to occur if the withheld information were to be disclosed.

93. The Commissioner further considers the prejudice will be the loss of the experienced researchers to other institutions that can guarantee them privacy and confidentiality, and that this is real. The Commissioner accepts that this is an important factor and affords significant weight to it.

94. QMUL maintains that, if the withheld information were to be disclosed, this would be likely to inhibit the effectiveness of the discussions which could result in poorer decision making, and perhaps inhibit some individuals from participating altogether.

95. The Commissioner recognises that should these minutes be disclosed, this would be likely to erode some of the trust that participants have that information they provide will not be made publicly available. As such the Commissioner considers this to be a relevant argument weighing in favour of maintaining the exemption.

96. Although there is a strong public interest in transparency and accountability in public authorities, the Commissioner considers this has been satisfied to some extent by the publication of the trial results.

97. Therefore the Commissioner's conclusion is that, in all the circumstances of the case, the public interest in maintaining the exemption outweighs the public interest in favour of disclosing the requested information.

98. The Commissioner considers that section 36(2)(b)(i) and 36(2)(b)(ii) can be applied to all the withheld information. He has therefore not gone on to consider the application of section 36(2)(c).

Right of appeal

99. Either party has the right to appeal against this decision notice to the First-tier Tribunal (Information Rights). Information about the appeals process may be obtained from:

    First-tier Tribunal (Information Rights)
    GRC & GRP Tribunals,
    PO Box 9300,
    LEICESTER,
    LE1 8DJ

    Tel: 0300 1234504
    Fax: 0116 249 4253
    Email: informationtribunal@hmcts.gsi.gov.uk
    Website: www.justice.gov.uk/guidance/courts-and-tribunals/tribunals/information-rights/index.htm

100. If you wish to appeal against a decision notice, you can obtain information on how to appeal along with the relevant forms from the Information Tribunal website.

101. Any Notice of Appeal should be served on the Tribunal within 28 (calendar) days of the date on which this decision notice is sent.

Signed .....

Pamela Clements
Group Manager, Complaints Resolution
Information Commissioner's Office
Wycliffe House
Water Lane
Wilmslow
Cheshire
SK9 5AF