

Freedom of Information Act 2000 (FOIA)

Decision notice

Date: 26 September 2012

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 information relating to a trial carried out for the treatment of chronic fatigue syndrome and subsequent deterioration rates.
2. The request was refused under section 22 of the FOIA (information intended for future publication).
3. The Commissioner's decision is that although section 22 is engaged the public interest favours disclosure of the information.
4. The Commissioner requires the public authority to take the following steps to ensure compliance with the legislation.
 - To provide the requested information to the complainant.
5. The public authority must take these steps within 35 calendar days of the date of this decision notice. Failure to comply may result in the Commissioner making written certification of this fact to the High Court pursuant to section 54 of the Act and may be dealt with as a contempt of court.

Request and response

6. On 29 March 2012, the complainant wrote to QMUL and requested information in the following terms:

'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 (separately) the proportion of participants who deteriorated by 8 points or more for SF-36 Physical Function.'

7. The QMUL responded on 3 April 2012. It denied holding the requested information.
8. Following an internal review the QMUL wrote to the complainant on 2 May 2012. It stated that it had mistakenly advised that the information was not held and therefore the request had been reconsidered. However, it went on to state that the information was exempt under section 22 of the FOIA – Information intended for future publication.

Scope of the case

9. The complainant contacted the Commissioner to complain about the way his request for information had been handled.
10. The Commissioner considers the scope of this request has been to consider whether section 22 was correctly engaged in this case.

Reasons for decision

11. Section 22 of FOIA states that information is exempt information if-
- (a) the information is held by the public authority with a view to its publication, by the authority or any other person, at some future date (whether determined or not),
 - (b) the information was already held with a view to such publication at the time when the request for information was made, and
 - (c) it is reasonable in all the circumstances that the information should be withheld from disclosure until the date referred to in paragraph (a).
12. In order to determine whether section 22 is engaged the Commissioner therefore needs to consider the following questions:
- Was the information requested held by the public authority?
 - When the request was submitted, did the public authority have an intention to publish the information at some date in the future?
 - If so, was this date determined when the request was submitted?
 - In all the circumstances of the case, is it 'reasonable' that information should be withheld from disclosure until some future date (whether determined or not)?

Was the information held by QMUL and was there an intention to publish at the time the request was received?

13. The QMUL states that at the time of the request it was believed that this information did not exist. However, after the complainant requested an internal review, the statistician who did all the main analyses for the PACE trial confirmed that the information was held. The Principal Investigator (PI) consulted with colleagues with whom he had conducted the trial. At that time the first draft of a paper on adverse events in the trial had been completed and it was agreed that these deterioration data would eventually form part of the paper when submitted for publication.

14. QMUL further stated that the publication date was not known at the time of the request, only that it would be in the foreseeable future. QMUL confirmed to the Commissioner during his investigation that the research team are in the middle of further analyses, including the data requested.
15. QMUL explained that this is not unusual with medical research papers as these have to be agreed by all co-authors, then submitted to a process of peer review which can last many months.
16. The Commissioner notes that QMUL's publication scheme states under its 'Research Data Management Policy' that "publically funded research data should be made openly available in a timely manner".
17. The Commissioner interprets the words in section 22 of 'with a view to' to indicate an intention has been made to publish or at the very least that the information is held in the settled expectation that it will be published. The publication date does not need to be definite for the exemption to apply. As long as a decision has been made that the information requested will be published at some time in the future or there is a settled expectation that this will happen, the exemption can be considered.
18. Publication requires the information to be generally available to the public. It is not enough if the intention is to make it available to a restricted audience.
19. The Commissioner notes that an article was published in The Lancet in March 2011 relating to the improvement rates in the trial.
20. If during the course of the preparation of the information for publication some material will be redacted, section 22 will not apply to the redacted information. This is because the public authority will no longer hold the information with a view to publication in the future.
21. The Commissioner accepts that all the information requested is intended for future publication at some point and that a draft of that publication is in progress.

Was it reasonable in all the circumstances to withhold the information prior to publication?

22. QMUL stated that withholding the information at this stage is crucial because it will allow proper publication of these data, including their interpretation, which has passed the scientific standard of peer and editorial review. QMUL believe that this prevents misinterpretation of research data, which they fear may occur with premature publication.
23. The Commissioner acknowledges that the argument provided by QMUL is a legitimate one to make. In reaching his decision he has taken into account the content of his Awareness Guidance in this subject in which he has considered whether QMUL have been sensible, fair to all concerned and acted in line with accepted practises to withhold this information prior to publication. Having done so he is prepared to accept that it was reasonable to do so.

Public interest arguments in favour or maintaining the exemption

24. Although the Commissioner has accepted that it is reasonable in the circumstances for the public authority to engage section 22 as a basis for withholding the requested information, the exemption can only be applied where the public interest in maintaining the exemption outweighs the public interest in disclosure. Some of the complainant's arguments as to reasonableness are also applicable when considering the balance of public interest and these are referred to below.
25. There is a public interest in ensuring that the data is not published prematurely with the risk of misinterpretation and incorrect conclusions being drawn from it which could then undermine the extensive work carried out. As explained by QMUL above maintaining the exemption at this time will allow proper publication of the data, including its interpretation which has passed the scientific standard of peer and editorial review.

Public interest arguments in favour of disclosure

26. QMUL does not appear to have considered what the public interest in disclosing the data would be. Therefore the Commissioner has formulated his own view on this and considered the complainant's arguments.

27. The complainant has argued that it is over a year since the publication of the PACE trial, and the deterioration rates are an essential part of the research.
28. The complainant further states that the improvement rates have already been published and that the deterioration rates are required so that clinicians can see both sets of data in order to make an informed judgement about the treatments that were investigated.
29. The complainant also states that the trial is a 100% publicly funded medical research project, so the data should be publicly available.
30. The complainant notes that some deterioration rates have been provided, but the deterioration rates by the specific measures, as he requested, have not been made public.

Balance of the public interest arguments

31. It is the Commissioner's view that the QMUL's fear of misinterpretation is not a valid argument. The data, as provided to the Commissioner could be used at any point post-publication, in isolation and out of context. In any event, the QMUL would be able to provide an explanation to contextualise the information if necessary.
32. There appears to be little evidence to support withholding the information requested. The Commissioner notes there is likely to be a public interest in such information and that disclosure would provide further information to the public debate on this issue.
33. It is noted that although QMUL has indicated its intention to publish the data, it has yet to determine a date. The Commissioner appreciates that clinical trial data is often a sensitive matter. However, the Commissioner notes that the improvement rates were published in an article in The Lancet in March 2005. Therefore, as some of the information is already in the public domain, in this case, improvement rates, it is important that balance is provided.
34. He has also again considered his Awareness Guidance which states that the public interest in releasing the information will often be stronger if the planned date of publication is far in the future, or where there is no firm indication of a likely date of

Reference: FS50451416

publication. In this case QMUL has not provided a firm indication of likely publication other than it will be in the foreseeable future.

35. It is the opinion of the Commissioner that although section 22 applies with regard to the matter of future publication, QMUL has failed to provide substantial arguments relating to the public interest test.
36. In this case the Commissioner considers that the public interest in disclosure outweighs the public interest in maintaining the exemption.
37. The Commissioner has therefore determined that the requested information should be disclosed.

Right of appeal

38. 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

39. 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.
40. 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