

Freedom of Information Act 2000 (FOIA)

Decision notice

Date: 29 July 2013

Public Authority: Medical Research Council
Address: One Kemble Street
London
WC2B 4AN

Decision (including any steps ordered)

1. The complainant has requested to know who owned and managed the raw data generated from a medical trial. The Medical Research Council (MRC) stated it did not hold information to answer this request.
2. The Commissioner's decision is that the MRC does not hold any information to answer this request and he is satisfied the MRC has complied with the provisions of the FOIA.

Background

3. The PACE Trial was one of the first large scale, randomised trials to evaluate the effectiveness of various treatment options for Chronic Fatigue Syndrome/Myalgic Encephalomyelitis (CFS/ME). Thus the trial required the collection of vast amounts of medical baseline and treatment results over the period 2005-2010 from the approximately 640 patients who participated in it.

Request and response

4. On 17 December 2012, the complainant wrote to the MRC and requested information in the following terms:

"Please could you tell me who does own and manage the raw data which was generated for the PACE trial?"

5. The MRC responded on 17 December 2012 and advised the complainant to contact Queen Mary, University of London (QMUL) as it led the study. The complainant responded on the same day to reiterate her request related to ownership and management of the data and as the MRC co-funded the study the complainant wanted to know who the MRC considered owned the data.
6. On 15 January 2013 the MRC responded and reiterated that data relating to MRC-funded studies would be owned and managed by the host institution, QMUL in this case. The MRC stated that QMUL would be able to confirm the position in relation to ownership, custodianship, management and access to the information generated from the PACE trial.
7. The complainant wrote back to the MRC on 16 January to express dissatisfaction that her question had not been answered. The complainant restated her request to know who the MRC regarded as owning the raw data generated by the trial.
8. Following an internal review the MRC wrote to the complainant on 21 February 2013. It stated that it had informed the complainant that the MRC did not hold the information and had provided the contact information to redirect the enquiry. The MRC went on to explain that having reviewed the request it now considered it was asking for an opinion and as the MRC did not hold any information that would answer the question, the request was not valid as the FOIA does not extend to unrecorded opinions.

Scope of the case

9. The complainant contacted the Commissioner on 13 February 2013 to complain about the way her request for information had been handled. In particular the complainant did not agree that the MRC would not hold the requested information as they were the body partly responsible for funding the study.
10. The Commissioner considers the scope of his investigation to be to determine if the MRC holds any information which is relevant to the request and could be used to answer the question asked by the complainant.

Reasons for decision

11. Section 1(1)(a) of the FOIA states that:

"Any person making a request for information to a public authority is entitled –

(a) to be informed in writing by the public authority whether it holds information of the description specified in the request,"

12. The Commissioner has considered whether the MRC has complied with this section of the FOIA in stating that it does not hold any information in response to the complainant's request.
13. Initially, the MRC explained it did not hold the requested information and QMUL would be more likely to be able to provide information on ownership and management of the PACE trial data. The complainant explained that as the study was MRC-funded it would stand to reason that the MRC would be able to offer a view on who owns the data and who is responsible for managing it. In the internal review response the MRC therefore considered the request was not a valid request as it was asking for an opinion and there was no information held which could answer the question.
14. The Commissioner wrote to the MRC and questioned it further on whether any information was held which addressed the issue of ownership and management of the data generated by the MRC-funded research. In determining whether any information was held he considered the standard of proof to apply was the civil standard of the balance of probabilities. In deciding where the balance lies in cases such as this one the Commissioner may look at:
 - Explanations offered as to why the information is not held; and
 - The scope, quality, thoroughness and results of any searches undertaken by the public authority.
15. The MRC in response provided some further background about the PACE trial and MRC's role in this study. The MRC explained that in 2004 it awarded grant funding to QMUL for a study entitled "The PACE trial". The grant was funded under the MRC's standard Terms and Conditions which is the main document outlining the relationship between the MRC and the institution receiving the funding. The MRC has been unable to locate a copy of the Terms and Conditions that applied at the time the study started but has located an earlier copy of the same document¹

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http://www.webarchive.org.uk/wayback/archive/20050816120000/http://mrcwebsite_marc_h_2000/fund_sch/rinfo_6.html#top

which contained a section on the exploitation of research results. In this section the Terms and Conditions state that:

"Ownership of any intellectual property arising from MRC grants is vested initially in the institution administering the award."

16. The Commissioner notes that this relates to any intellectual property rights which may arise from the trial but is not specifically in relation to ownership or management of the data. The MRC also provided a link to its current Terms and Conditions that apply for MRC-funded grants². The relevant section in this is GC21 which states that:

"Unless stated otherwise, the ownership of all intellectual assets, including intellectual property, and responsibility for their application, rests with the organisation that generates them."

17. The Commissioner has considered this and whether these Terms and Conditions set out the position with regards to who owns and manages the data generated by the PACE trial study. He is of the view that the Terms and Conditions clearly specify the situation with regards to intellectual property which the MRC considers also covers any findings including data collected or generated during the study, but cover general situations and are not specific to the PACE trial study.
18. For this reason the Commissioner does not consider these Terms and Conditions to contain the information sought by the complainant and in any event the recent iteration of these Terms and Conditions is publicly available.
19. The MRC has explained that based on these general Terms and Conditions it would therefore expect that QMUL would own any data collected or generated by the trial and the MRC would not normally hold any rights or ownership or management of findings of MRC-funded research grants.
20. However, the MRC has acknowledged that in some cases a grant-holding institution may make alternative arrangements for the ownership and
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management of data. In some cases where clinical trials take place responsibilities may also be dependent on the consent provided by participants or on arrangements with participating centres. However, in such cases the MRC maintains that only the sponsor for the study would be able to confirm the position with regards to ownership, management and access. As QMUL was the institution responsible for administering the award and the sponsor for the study the MRC considers QMUL to be the only body able to address the issue of ownership and management of the data relating to the PACE trial study.

21. The MRC has explained that on receipt of the request it consulted with the Principal Investigator for the study and the Freedom of Information Officer at QMUL and considered there was nothing other than the standard Terms and Conditions for MRC grants that would be applicable and this was not specific to the PACE trial. Following the consultation with the Principal Investigator, the MRC has provided copies of correspondence which suggest the issue of ownership was not entirely clear but was believed to rest with QMUL. As the MRC considered the request to be asking for an opinion on whom the MRC believed owned and managed the data the MRC therefore informed the complainant that it did not hold information to answer the question and suggested QMUL would be better placed to respond.
22. However, following contact from the Commissioner, MRC conducted a review of the files it held relating to the PACE trial to ensure no recorded information was held which specifically or explicitly addressed the matter of ownership and management of the data relating to the PACE trial.
23. The MRC searched the three paper files it held relating to the PACE trial for any relevant information. These files contained documents such as the grant application and award and acceptance letters. The only indication in these documents as to who would own and manage data is a reference to the standard MRC grant Terms and Conditions applying.
24. A search of the MRC's electronic records was also conducted to identify any information relating to the PACE trial and establish if the issue of ownership and/or management of the data was referenced. Whilst the MRC did find a number of documents there were no specific or explicit references to ownership or management of the PACE trial data. Two sets of Terms and Conditions were referred to in award letters: the Terms and Conditions from 2000 (link provided at footnote 1) and the Terms and Conditions from 2004. The MRC has been unable to locate a copy of the latter of these documents despite searching its electronic and paper records, its publications archive and consulting with other teams within the MRC.

25. The Commissioner accepts in this case the request is worded in such a way as to be unclear as to whether it is requiring the MRC to supply any recorded information on the issue of ownership and management of the data or whether it is asking for the MRC's opinion on who owns and manages the data. However, the Commissioner's view is that either way the MRC was obliged to establish if any recorded information was held that discussed the issue of ownership and management of the data.
26. Taking into account the explanations provided by the MRC and on balance the Commissioner accepts that the MRC has been unable to find any information which specifically addresses this issue. The MRC has located its standard Terms and Conditions but these are not specific to different trials, particularly ones with a clinical element. As the MRC could not answer the request it directed the complainant as the administrator and sponsor of the study as the most likely body to be able to answer the question and as the body the MRC considered most likely to be responsible for owning and managing the data generated by the PACE trial study. Based on the explanations provided by the MRC the Commissioner is therefore satisfied that MRC has conducted adequate searches to reach the position that it does not hold information to answer the request.
27. Taking into account all of the above, the Commissioner therefore considers that the MRC complied with section 1(1)(a) of the FOIA.

Right of appeal

28. 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

29. 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.
30. 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
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