

Freedom of Information Act 2000 (FOIA)

Decision notice

Date: 14 July 2020

Public Authority: Kings College London (KCL)
Address: Room 5.35
James Clerk Maxwell Building
57 Waterloo Road
London SE1 8WA

Decision (including any steps ordered)

1. The complainant has requested information relating to 'Comparison of adaptive pacing therapy, cognitive behaviour therapy, graded exercise therapy, and specialist medical care for chronic fatigue syndrome (PACE): a randomised trial'. KCL refused to disclose some of the requested information under section 22A and 40(2) FOIA and argued that some of the requested information either was not held by KCL or alternatively it would exceed the cost limit under section 12 FOIA to locate, retrieve and extract it.
2. The Commissioner's decision is that section 22A FOIA was applied correctly to some of the requested information and it would exceed the cost limit under section 12 FOIA to locate, retrieve and extract the remaining requested information.
3. The Commissioner requires no steps to be taken.

Request and response

4. On 6 June 2019 King's College London responded to a request originally made by the complainant in 2018 as a result of the First Tier Tribunal decision in EA/2018/0242. The Tribunal found that on the balance of probabilities the requested information was held by KCL. The original request was for the following information:

"These requests concern 'Comparison of adaptive pacing therapy,

cognitive behaviour therapy, graded exercise therapy, and specialist medical care for chronic fatigue syndrome (PACE): a randomised trial'. The requests are made to KCL as a joint holder of the data.

I am asking for anonymized data, as determined by the Information Tribunal (IT) decision in QMUL V The Information Commissioner & Matthees
(PDF)

[http://informationrights.decisions.tribunals.gov.uk/DBFiles/Decision/i1854/Queen%20Mary%20University%20of%20London%20EA-2015-0269%20\(12-8-16\).PDF](http://informationrights.decisions.tribunals.gov.uk/DBFiles/Decision/i1854/Queen%20Mary%20University%20of%20London%20EA-2015-0269%20(12-8-16).PDF)

I would, if I may, refer you in particular to the following parts of the decision by the IT. The IT was clear:

First, the test for whether data can be released is simple: whether the data can be anonymized.

Second, the test as to whether the data can be anonymized is not absolute. The test is whether the risk of identification is reasonably likely, not whether it is remote, and whether patients can be identified without prior knowledge, specialist knowledge or equipment, or resort to criminality.

Third, where data can be anonymized, there is no legal or ethical consideration which prevents release, and that there is nothing in the consent forms preventing release.

Fourth, where data can be anonymized, there is a strong public interest in release; making data available advances legitimate scientific debate; and data should be released.

Please provide the following patient-level data for baseline, 12-week, 24-week and 52-week assessments, where available.

- 1. EuroQOL (EQ-5D) scores.*
- 2. Hospital Anxiety and Depression Scale scores in both anxiety and depression sub-scales.*
- 3. Work and Social Adjustment scale scores.*
- 4. Borg Scale scores*
- 5. Physical Health Questionnaire 15 items (PHQ15) scores.*
- 6. Self-paced step test of physical fitness results*
- 7. Client Service Receipt Inventory scores. (Please also include the 6-months-prior assessment.)*
- 8. Jenkins Sleep Scale scores.*
- 9. Self-efficacy Scale scores."*

5. On 6 June 2019 KCL confirmed it held information relevant to the scope of the request but refused to disclose this under section 22A FOIA.
6. The complainant requested an internal review and the result of this was provided on 29 July 2019 in which KCL maintained its original position.

Scope of the case

7. The complainant contacted the Commissioner to complain about the way his request for information had been handled.
8. During the course of the Commissioner's investigation KCL confirmed that parts 2, 3, 4, and 8 (5 and 9 shortly to follow) were available on the Dementias Platform UK (DPUK) at:

<https://www.dementiasplatform.uk/>

It confirmed that anyone can apply for the data with a research proposal and analytic strategy. However it said it continued to apply section 22A and 40(2) to withhold this information from disclosure under FOIA.

9. It said it continued to be of the view that parts 1 and 7 of the request were not held by KCL but said that in the alternative it would exceed the cost limit to locate, retrieve and extract this information.
10. The Commissioner has considered whether KCL was correct to apply section 22A and 40(2) to parts 2-5 and 8-9 of the request. She has also considered whether KCL holds the information requested at parts 1 and 7 of the request and if so whether it would exceed the cost limit to locate, retrieve and extract this information.

Reasons for decision

Section 22A

11. Section 22A exempts the following information from disclosure:
 - (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).

12. The exemption is qualified and is subject to a public interest test.

Information from a programme of research

13. The Commissioner's Guidance¹ explains that:

"The exemption applies to information 'obtained in the course of, or derived from, a programme of research', where the research is ongoing, and there is a plan to publish a report of the outcome. Any such report may or may not include the information that has been requested, without affecting the application of the exemption to the information.

The exemption will include a wide range of information relating to the research project, and will cover information that is not necessarily going to be published. In other words there does not need to be any intention to publish the information that has been requested.

FOIA does not define 'research'. The Commissioner will use the ordinary definition of the term research: a systematic investigation intended to establish facts, acquire new knowledge and reach new conclusions."

14. KCL confirmed that the requested information derives from 'Comparison of adaptive pacing therapy, cognitive behaviour therapy, graded exercise therapy, and specialist medical care for chronic fatigue syndrome (PACE): a randomised trial'.

¹ <https://ico.org.uk/media/for-organisations/documents/1172/information-intended-for-future-publication-and-research-information-sections-22-and-22a-foi.pdf>

15. The Commissioner is satisfied that the requested information derives from the PACE trial and is therefore information from a programme of research.

Ongoing programme of research

16. In order for the exemption to be engaged the programme of research must be ongoing.
17. In this case the complainant has argued that there has not been any research conducted on PACE at KCL for some years.
18. KCL has confirmed that it has checked with the principal investigator at KCL who has confirmed that the research programme is very much still ongoing.
19. As KCL has confirmed that the programme of research is ongoing this criteria can be met.

Intention to publish a report of the research

20. The Commissioner's guidance explains that:

"The exemption requires that the research programme must be 'continuing with a view to the publication... of a report of the research (whether or not including a statement of that information)'."

21. KCL has said it is doing an analysis of moderators/predictors of outcome as well as exploring clusters and how this affects outcome. The data is currently being analysed so KCL does not have a draft paper yet. KCL also has a PhD submission which it will use as the basis for further papers.
22. In this case KCL has confirmed that the research programme is currently in the process of writing the papers, which may take longer than anticipated due to the coronavirus pandemic.
23. It has confirmed that when complete, there is an intention for papers to be published. The principal investigator has confirmed that KCL will itself be publishing the papers
24. The Commissioner's guidance goes on to explain that:

"The exemption requires that the research programme is continuing 'with a view to the publication, by a public authority or any other person...' of a report of the research. Unlike section 22 where the public authority must

have an intention to publish the requested information, even if this is actually carried out by another body, in section 22A any individual, body corporate, public body or private organisation could have the intention to publish a report.

25. Based upon KCL's submissions it appears that there is an intention to publish a report of the research and this criteria is also therefore met.

Prejudice to the research or related interests

26. The Commissioner's guidance confirms that:

"The public authority must demonstrate that there is a risk that disclosure of the requested information before the envisaged date of publication would or would be likely to prejudice:

- *the research programme;*
- *the interests of an individual participating in the programme;*
- *the interests of the authority holding the information; or*
- *the interests of a different authority that is going to publish a research report.*

27. In this case KCL has explained that disclosure of the information at this point in time, ahead of the future publication of papers from this study, could prejudice the peer review process. 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 in order to ensure scientific rigour is maintained and that maximum value is achieved from the public investment. To not allow for an appropriate and adequate peer review would lower the dependability of the work and devalue the work already done. It would not be possible to mitigate against this by providing explanatory commentary with such a disclosure ahead of publication.

28. Similarly, it went on that, disclosure may lead to the study being undercut by other researchers. The release of the data may allow others to perform their own analysis and publish their findings without having to go through the process of collecting the data themselves, thereby giving them considerable advantage over the current study.

29. KCL referred to the Commissioner's 's guidance on the use of this exemption, and considers that it supports their view that such trials

should be allowed the proper time to carry out and complete their research without the undue pressure that such a disclosure would place on them. This allows the researchers to finalise their findings and publish all necessary reports under the best conditions. This in turn allows for the best quality research outputs.

30. Finally KCL said that the ethics committee that oversees this study has explicitly stated that information should not be released. While KCL is not bound by this directive when considering disclosure under the FOIA, it does enter into its considerations. While the information requested may not in itself directly identify individuals within the dataset, combining it with information previously disclosed under the FOIA by collaborating organisations increases the likelihood that an individual could be identified despite steps taken to try and avoid such an outcome. Accordingly, KCL considers the chance of an individual being identified to be more than remote (this is why it has also applied section 40(2) (Personal information) FOIA to this information).
31. The Commissioner considers that KCL has clearly explained how it considers disclosure would be likely to prejudice the research programme and the interests of an individual participating in the programme.
32. The Commissioner therefore considers that section 22A FOIA was correctly engaged in this case. She has therefore gone on to consider the balance of the public interest.

Public interest test

Public interest arguments in favour of disclosure

33. KCL acknowledged that there is a public interest in transparency of research carried out by the University. This specific study has led to particular public attention, and as such increasing transparency in the study could be considered to be in the public interest. The PACE trials have been very controversial and there is active opposition to the research.

Public interest arguments in favour of maintaining the exemption

34. At the time of the request, KCL were arranging for data to be uploaded onto the Medical Research Council (MRC) Dementias Platform UK (as explained above this has now been complete in relation to parts 2, 3, 4, 6 and 8 of the request and part 5 and 9 are soon to follow). This is a free-to-access resource with controlled access where researchers can

apply with a protocol and aims and hypotheses. Data will remain on the platform and be monitored while analysis is carried out to ensure plans are followed.

35. It said that the public interest favours data being made available in a controlled and focused manner by the MRC, whose aims are to accelerate progress and open up research. It is not in the public interest to divert time, effort and cost away from this data sharing initiative, and the research itself. It is also not in the public interest to make such research data freely available to the general public at this time; this could lead to anyone conducting analysis which does not confirm to the usual standards (e.g. protocols and specific hypotheses) thereby weakening the whole scientific process.

Balance of the public interest

36. The Commissioner considers there is a strong public interest in transparency behind a research study such as the PACE trial. There is significant public interest due to the controversy and criticism of this trial.
37. The Commissioner also considers that there is a strong public interest in not publishing the trial data in a way which could undermine the research process whilst it is ongoing. The public authority should be given time to present its conclusions, without the premature disclosure of information which may allow others to undermine any conclusions by criticising the data which underpins it or presenting their own conclusions based on that data.
38. The Commissioner is mindful in this case that much of the requested information can now be applied for in a controlled way via the Medical Research Council with a research proposal and analytical strategy.
39. On balance in this case, the Commissioner considers that the public interest in favour of disclosure is outweighed by the public interest in maintaining the exemption in this case.
40. As the Commissioner has found that section 22A is applicable to parts 2-6 and 8-9 of the request, she has not gone on to consider the application of section 40(2) FOIA to this information any further.

Section 1

41. In relation to whether or not KCL holds the information requested at parts 1 and 7 of the request, in EA/2018/0242, at paragraph 14 of the decision it explains that:

"In the IC's Response to [name redacted] appeal dated 9 January 2019 (and presumably because of the detailed arguments set out by [name redacted]) the IC indicated that it now agreed that KCL did in fact hold the requested information. The IC submitted that the appeal should be allowed but that KCL (who are not a party to the appeal) should be given an opportunity either to disclose the requested information or to state whether it relied on any other exemptions within FOIA. In particular, the IC felt that that the 'costs limit' exemption in s.12 FOIA might be relied on."

42. The Commissioner does not therefore intend to reconsider the issue of whether or not the information is held by KCL in this Notice.

Section 12

43. Section 12 of the FOIA allows a public authority to refuse to deal with a request where it estimates that it would exceed the appropriate cost limit to:

- either comply with the request in its entirety, or
- confirm or deny whether the requested information is held.

44. The estimate must be reasonable in the circumstances of the case. The appropriate limit is currently £600 for central government departments and £450 for all other public authorities. Public authorities can charge a maximum of £25 per hour to undertake work to comply with a request - 24 hours work for central government departments; 18 hours work for all other public authorities. If an authority estimates that complying with a request may cost more than the cost limit, it can consider the time taken to:

- (a) determine whether it holds the information
- (b) locate the information, or a document which may contain the information
- (c) retrieve the information, or a document which may contain the information, and
- (d) extract the information from a document containing it.

45. The appropriate limit for KCL is £450 or the equivalent of 18 hours work.

46. In terms of providing a copy of the information requested at parts 1 and 7 of the request, KCL said that this would be extremely difficult and expensive to do. It said it would have to employ a statistician with the necessary skillset to extract the requested information from the raw dataset.
47. This would involve running a recruitment campaign (writing a business case and applying for management approval for the post; writing a job description/person specification; writing a job advert; reviewing, shortlisting and interviewing applicants etc).
48. The successful candidate (presuming KCL manage to find someone as this would not be a particularly attractive role) would then need several days to get acquainted with the data and to put it into the right format. KCL estimated this would take two weeks' work at the very least.
49. Initially KCL said that the only staff member who has the expertise required to work on this data is not funded for data management purposes. This staff member is expected to do her own research leading directly to the production of publications. However subsequently KCL clarified that, the principal investigator had confirmed that the member of staff previously referred to as having "the expertise required to work on this data" would not be able to provide the economic data under (1) and (7) as she does not have the expertise to extract this from the raw dataset – an economist would be required. The economist previously attached to the study is no longer at KCL.
50. The complainant has disputed that an economist would be required to extract the information.
51. Given KCL's position is that it would be required to find an external individual with relevant expertise to extract the requested information from the raw data and then even once a suitable individual were found they would need to become acquainted with the data, this is going to create a time and cost implication to enable KCL to be in a position to be able to comply with the request. This individual would then need to begin work to locate, retrieve and extract the data which KCL has estimated is approximately two weeks work. Even if this were reduced down to 2 or 3 days this would exceed the cost limit. The Commissioner is therefore satisfied that to comply with parts 1 and 7 of the request would exceed the cost limit under section 12 FOIA.

Right of appeal

52. 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: 0870 739 5836
Email: grc@justice.gov.uk
Website: www.justice.gov.uk/tribunals/general-regulatory-chamber

53. 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.
54. 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.....

Gemma Garvey
Senior Case Officer

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