

Freedom of Information Act 2000 (FOIA)

Decision notice

Date: 12 August 2014

Public Authority: Barts Health NHS Trust (Royal London Hospital)

Address: Whitechapel Road
Whitechapel
London E1 1BB

Decision (including any steps ordered)

1. The complainant has requested information about the protocols for a drug trial. Barts Health NHS Trust ('the Trust') said it did not hold this information.
2. The Commissioner's decision is that the Trust does not hold the information and he does not require it to take any further steps.

Background

3. One of the complainants took part in a drug trial in 1986-1987 at the Royal London Hospital. The drug involved had been developed by a company called Sanofi. The complainant alleges that they received unnecessary treatment and subsequently had ongoing health problems, both as a result of their participation in the trial. In the course of pursuing a wider complaint against the Trust, other information that the Trust initially said it did not hold or had been mislaid, was later found.

Request and response

4. On 13 September 2013, the complainant wrote to Barts Health NHS Trust and requested information in the following terms:

"I want the protocols for the Danazol drug trial 1986-1987"

5. The Trust asked for more details on 25 September, which the complainant provided, and on 5 December the Trust responded. It said that although it was able to confirm that the complainant took part in the trial, it could not find any records or research relating to it.
6. In correspondence dated 9 January 2014, the Trust told the complainants that the document retention schedule that was in place in 1986-1987 required the master records of drug trials to be reviewed after 15 years. The Trust said that, in accordance with this policy, its records indicated that the records for the Danazol drug trial, including the protocols, would have been reviewed in 2002 and disposed of at that time.
7. Following an internal review the Trust wrote to the complainant on 18 March. It upheld its original position that it did not hold the information.
8. The complainants had also approached Sanofi (which, as a private company, is not subject to the FOIA) and asked for a copy of protocols. In a letter dated 3 February, Sanofi's Medical Director told the complainants that it did not issue clinical trial protocols to patients and this information should be sourced from the healthcare professional and trial investigator responsible for the patients' care – Royal London Hospital in this case.
9. The Medical Director explained that the drug trial in question had been an 'Investigator Sponsored Trial'. This means that the trial had been initiated by the Royal London Hospital, with Sanofi's role being to provide financial support to it. In terms that are perhaps not quite clear, the Director said that any documents such as protocols would therefore not belong to Sanofi and would not be theirs to release. The complainant subsequently confirmed to the Commissioner that they had been told by Sanofi some years previously that it did hold the protocols but that only medical staff could see this material.

Scope of the case

10. The complainant contacted the Commissioner on 6 February to complain about the way their request for information had been handled. In light of their past experience with the Trust, they did not accept that the Trust did not hold the protocols.
11. The Commissioner has focussed his investigation on whether the Trust is correct when it says that the Royal London Hospital does not hold the information that has been requested.

Reasons for decision

12. Section 1 of the FOIA says that an individual who asks for information is entitled to be informed whether the information is held and, if the information is held, to have that information communicated to them.
13. In its submission to the Commissioner, the Trust has outlined what searches it undertook for the information and explained aspects of its document and records keeping practices.
14. One of its electronic records databases flagged that the complainant had made enquiries about the Danazol trial records, but that no records had been found.
15. A search of the Trust's paper records indicated that a search for the protocols had been negative as the records had been disposed of in line with the Trust's Retention and Disposal Policy. At the time of the trial, this required associated records to be kept for 15 years after the trial ended ie 1987.
16. The Trust told the Commissioner the protocols would therefore have been destroyed in 2003 but acknowledged that it does not have a formal record of the disposal.
17. Section 3 of the FOIA says that:

"For the purposes of this Act, information is held by a public authority if
 - (a) it is held by the authority, otherwise than on behalf of another person, or*
 - (b) it is held by another person on behalf of the authority."*

18. The Commissioner's guidance, 'Information held by a public authority for the purposes of the Freedom of Information Act'¹, says that when information is held by another person on behalf of a public authority, the information is held by the public authority for the purposes of the FOIA.
19. In this case, if the Trust had a contractual arrangement with Sanofi that required Sanofi to hold the protocols in question 'on behalf of' the Trust, the Trust could be said to hold the information through this arrangement. Although Sanofi has confirmed to the complainants that it holds the protocols, the Trust has told the Commissioner that Sanofi is not holding the information on behalf of the Trust. There is not therefore an arrangement in place here through which the Trust could be said to hold the information for the purposes of the FOIA.
20. Having considered the submission that the Trust has provided to him, the Commissioner is satisfied that, on the balance of probabilities, the Trust does not hold the information that has been requested and has complied with section 1 of the Act.

Other matters

21. The Commissioner notes that the Trust does not have a record of the requested information's destruction. The Commissioner reminds the Trust that there are a number of benefits to good record and information management, one of which is to those requesting information because it provides some assurance that the information provided is complete and reliable.

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http://ico.org.uk/for_organisations/guidance_index/~media/documents/library/Freedom_of_Information/Detailed_specialist_guides/information_held_by_a_public_authority_for_purposes_of_foia.ashx

Right of appeal

22. 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: grc@hmcts.gsi.gov.uk

Website: www.justice.gov.uk/tribunals/general-regulatory-chamber

23. 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.
24. 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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