

Freedom of Information Act 2000 (FOIA)

Decision notice

Date: 26 January 2017

Public Authority: University College London Hospitals

Address: 250 London Road
London NW1 2PG

Decision (including any steps ordered)

1. The complainant has requested information concerning a consortium trial. University College London Hospitals (UCLH) released some information. The complainant disputes that UCLH has released all the relevant information that it holds.
2. The Commissioner's decision is that, on the balance of probabilities, UCLH has disclosed all the relevant information that it held at the time of the request and has complied with its obligations under section 1(1) of the FOIA.
3. UCLH breached section 10(1) however, as it did not comply with section 1(1) within 20 working days.
4. The Commissioner does not require UCLH to take any steps.

Request and response

5. On 23 April 2016, the complainant wrote to UCLH and requested information in the following terms:

"... my FOIA also covers the request for the empty consent form and the patient information sheet for the Videregen/INSPIRE Consortium trial, to be conducted at UCL/UCLH and led by Prof Martin Birchall."
6. UCLH responded on 25 April 2016 and said it did not hold the requested information concerning the Inspire trial.
7. UCLH acknowledged the complainant's request for an internal review on 8 June 2016 and apologised for having initially misunderstood his request. UCLH provided an internal review on 17 August 2016 and disclosed information that it had identified that it held. This was a particular Patient Information Sheet (PIS). UCLH said the PIS was under review but it would be pleased to send the complainant an updated version when it was available.

Scope of the case

8. The complainant initially contacted the Commissioner on 17 June 2016 to complain about the way his request for information had been handled.
9. The complainant is dissatisfied with the information he subsequently received from UCLH following its internal review. He told the Commissioner that UCLH had released deliberately misleading information to him, namely an 'outdated' version of the PIS dated January 2015, which it had described as the most recent version. The complainant said that he had obtained a more recent version of the PIS, namely version 5.0 dated May 2016, from another source.
10. The Commissioner's investigation has therefore focussed on whether UCLH complied with section 1(1) of the FOIA and disclosed all the relevant information that it held at the time of the request. The Commissioner has also considered the length of time it took UCLH to comply with section 1(1).

Reasons for decision

Section 1 – right of access

11. Section 1(1) of the FOIA says that anyone who requests information from a public authority is entitled a) to be told whether the authority holds the information and b) if it is held, to have the information communicated to him or her. A public authority is only obliged to release information that it holds at the time it receives a request.
12. In its submission UCLH first told the Commissioner that the information that it released to the complainant on 17 August 2016 was a Patient Information Sheet (PIS) dated January 2016, and not January 2015 as the complainant had told the Commissioner.
13. UCLH went on to say that its Research and Development department has an on-line, secure store of all documents for studies taking place at UCLH. Before a study takes place at UCLH, permission is provided by the Department. The permission process checks all documents corresponding to those which should be in use (ie approved by research regulatory approvals). All these documents are uploaded to this system and then the permission is granted.
14. UCLH confirmed that it searched this data base in order to ascertain the most recent version of the Patient Information Sheet it held, which it released to the complainant.
15. UCLH says that the particular study in question was provided with NHS permission in May 2016. The approval was provided based on the Patient Information Sheet which corresponds to the regulatory approval (Ethical Approval) dated 7th January 2016. This Ethical Approval lists the Patient Information Sheet entitled "PIS UK Master v3.0 15th December 2015". This is the Patient Information Sheet which the Department had approved to be used.
16. The Commissioner notes that having told her that the PIS released to the complainant was dated January 2016 (paragraph 12), UCLH's submission then says that version 3.0 of the PIS dated 15 December 2015 was therefore the Patient Information Sheet it provided to the complainant in response to his request.
17. UCLH confirmed that it conducted its search at the time that the complainant's request was first submitted to the Department. A later version of the PIS, version 4, was provided to UCLH after his request had been received. UCLH told the Commissioner that the trial Sponsor notified it in November 2016 of the approval of a 6th version of the PIS. UCLH says it is awaiting further details of this version. It has confirmed

that it has not received version 5, nor subsequent versions, from the Sponsor.

18. UCLH's position is therefore that it did not hold version 5 of the PIS at the time it received the complainant's request. It released to him the version it did hold, namely version 3.
19. During correspondence with the Commissioner, the complainant provided her with version 3.0 of the PIS which he says that UCLH released to him and version 5.0 of the PIS which the Oxford Research Ethics Commission (REC) released to him in response to separate FOIA request.
20. The complainant appears to consider that UCLH "secretly" changed an approved medical protocol; that is, the PIS. He has noted that both version 3.0 and version 5.0 of the PIS are labelled at the bottom: '*CLIN-FORM-20 Version 1.0 Effective Date 17 01 2014*' and queried why, if these labels are the same, the two documents are 'utterly different'.
21. The Commissioner notes that version 3.0 of the PIS is, however, labelled at the top '*PIS UK Master v3.0 – Date 15Dec15; Local UCLH v1.0 – Date 05Jan16*'. Version 5.0 of the PIS is labelled at the top: '*UK Master; Version 5.0; Date 05May2016*'. This would explain to the Commissioner why the two versions are different; because one is a later version than the other.
22. The complainant also says that UCLH provided version 5.0 of the PIS to the REC and therefore it must have held this version at the time of his request.
23. The complainant has provided to the Commissioner other information that the REC released to him. This includes a letter from the Health Research Authority dated 7 January 2016. This is the Ethical Approval UCLH has referred to at paragraph 15, and which it may also have been referring to at paragraph 12.
24. The Commissioner notes that the version of the PIS referred to in a table of 'Approved Documents' in the Ethical Approval is version 3.0, dated 15 December 2015.
25. It therefore appears to the Commissioner more likely that *if* UCLH provided a Patient Information Sheet to the REC, it was version 3.0 and not, as the complainant asserts, version 5.0. The REC may well have held version 5.0 of the PIS which it released to the complainant. However the Commissioner has not been persuaded that it was UCLH that provided version 5.0 to the REC. Version 3.0 is the version that UCLH says it held at the time of the request and so this was the version it released to him.

26. Having considered UCLH's and the complainant's submissions, the Commissioner finds UCLH's submission more convincing. She is therefore prepared to accept that UCLH has released to the complainant all the relevant information it held at the time of the request – that is, version 3.0 of the Patient Information Sheet.

Section 10 – time for compliance

27. Section 10(1) of the FOIA says that public authorities must comply with section 1(1) promptly and within 20 working days.
28. In this case, the complainant submitted his request on 23 April 2016 and information was not released to him until 17 August 2016. The Commissioner has noted UCLH's explanation for the delay and that it apologised to the complainant for it. However as the information was released outside 20 working days UCLH did not comply with the requirements of section 10(1) when responding to the complainant.

Right of appeal

29. 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@hmcts.gsi.gov.uk
Website: www.justice.gov.uk/tribunals/general-regulatory-chamber

30. 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.
31. 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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