Freedom of Information Act 2000 (FOIA)

Decision notice

Date:	**17 April 2025**
Public Authority:	**Royal Free London NHS Foundation Trust**
Address:	**Pond Street** **Saint Johns Wood** **NW3 2QG**

Decision (including any steps ordered)

1. The complainant has requested information on whether a particular batch number was on a vial of cells provided for administration to a patient.

2. The Commissioner's decision is that Royal Free London NHS Foundation Trust ("the Trust") is entitled to rely on section 40(2) of FOIA to withhold the requested information as it is special category personal data of an individual and disclosure would be unlawful.

Request and response

3. The complainant made a request for information in August 2024 following on from an earlier request responded to on 6 October 2020. The request asked:

"I would like to ask a follow-up question on the response below. Regarding the questions about Celixir's press release, question 2 asked "did the Royal Free provide a vial of Celixir's frozen cells to the Royal Brompton for administration to the patient on 16th March?" Your replied "Yes".

1) I would like to ask if the vial that was provided was labelled "CLXR-H-18-004-3" or "CLXR-HPL-19-002".

4. The Trust responded on 4 September 2024. It stated that it held information but considered it exempt under section 40(2) FOIA.

5. The complainant requested an internal review of this decision on 5 September 2024. They argued that revealing the reference code of the vial of cells that were delivered would simply show if the vial contained cells or a placebo but did not consider this would lead to the patient being identified.

6. The Trust conducted an internal review and responded on 4 December 2024 upholding its decision.

Scope of the case

7. The complainant contacted the Commissioner on 10 November 2024 to complain about the Trust's refusal of their request.

8. The Commissioner considers the scope of his investigation is to determine if the Trust has correctly applied section 40 FOIA to withhold the requested information.

Reasons for decision

Section 40 – personal information

9. Section 40(2) of FOIA provides that information is exempt from disclosure if it is the personal data of an individual other than the requester and where one of the conditions listed in section 40(3A)(3B) or 40(4A) is satisfied.

10. In this case the relevant condition is contained in section 40(3A)(a). This applies where the disclosure of the information to any member of the public would contravene any of the principles relating to the processing of personal data ('the DP principles'), as set out in Article 5 of the UK General Data Protection Regulation ('UK GDPR').

11. The first step for the Commissioner is to determine whether the withheld information constitutes personal data as defined by the Data Protection Act 2018 ('DPA'). If it is not personal data then section 40 of FOIA cannot apply.

12. Secondly, and only if the Commissioner is satisfied that the requested information is personal data, he must establish whether disclosure of that data would breach any of the DP principles.

Is the information personal data?

13. Section 3(2) of the DPA defines personal data as:

"any information relating to an identified or identifiable living individual".

14. The two main elements of personal data are that the information must relate to a living person and that the person must be identifiable.

15. An identifiable living individual is one who can be identified, directly or indirectly, in particular by reference to an identifier such as a name, an identification number, location data, an online identifier or to one or more factors specific to the physical, physiological, genetic, mental, economic, cultural or social identity of the individual.

16. Information will relate to a person if it is about them, linked to them, has biographical significance for them, is used to inform decisions affecting them or has them as its main focus.

17. The complainant argues that the request asks whether a batch of cells provided to a patient on a specific date had a particular label. Celixir, the company who manufactured the cells, had recently been investigated by the Medicines and Healthcare Regulatory Authority (MHRA) and an infringement notice was served. This notice stated:

"… however, the trial commenced, and a single patient was dosed"

with a footnote going on to state that:

"It was subsequently confirmed that the patient in question had been administered a placebo."

18. The complainant was sceptical about this statement as Celixir themselves had indicated in a press release that cells had been administered, not a placebo. They had serious concerns that Celixir had only escaped charges because they stated the patient received a placebo and therefore knowing the reference code of the vial that the Trust delivered to the Royal Brompton Hospital could clarify whether the cells were live or a placebo. The complainant did not consider this could lead to a patient being identified.

19. The Trust agreed that the batch number itself could not identify an individual on its own but explained to the Commissioner this was not the basis of the Trust's application of section 40(2) FOIA.

20. The Trust considered the patient could be identified by other means by the complainant, the data subject themselves or the data subject's

friends and/or family. This may be via information already known to them or when combined with information from other sources.

21. The Trust considered the Commissioner's guidance on indirect identification, in particular the motivated intruder test using the benchmark of an investigative journalist. The Trust found there are likely to be new articles, academic papers and investigation reports relating to this case available in the public domain.

22. It argued that the complainant themselves may well have detailed knowledge of the investigation as they were able to provide the batch numbers from the vials when making the request for information. This increases the risk of the data subject being identified, particularly as the scope of the request relates to one specific patient rather than a cohort. This is in addition to those who may already know who the data subject is, such as friends and colleagues.

23. The Commissioner was not convinced that the batch number itself could lead to the identification of an individual, in this case the individual who received the vial on the specified date. His view is that information in a new report or academic paper might lead a friend, colleague or interested party to put the pieces together and identify if a particular person was involved in a study. It seems that identification could happen without the batch number.

24. The Trust clarified it's engagement of section 40(2) was not solely based on whether the batch number could identify the data subject but whether disclosing the information would reveal new information about them and therefore breach the data protection principles.

25. It considered the motivated intruder test and whether the patient is identifiable or already known to the requester or 'any other person' as answering the request would be placing the information into the public domain. The Trust considered it was likely that, at a minimum, the data subject themselves, family members or close friends would be able to identify the patient from the scope of the question asked which was "the first patient was treated on 16th March 2020". This scope was established from the previous information request to which this request is a follow-up. The Trust believes the complainant has detailed knowledge of the trial and the MHRA investigation that followed and is clearly motivated in investigating the broader clinical trial.

26. Confirming what label was on the vial the Trust states would reveal whether the patient received the cell therapy or the placebo during the clinical trial. This is clinical information about one specific person and what was biologically administered to them. Medical information on whether the patient was given the therapy or not may be new

information to people who did not previously know it. This could include the colleagues, friends, or family members of the patient, as well as any motivated persons. If it was already known information, the Trust considers the FOIA request would not be necessary. Disclosure would therefore breach the data protection principles.

27. The Commissioner agrees that confirming the batch number could reveal information not previously known about the patient. It seems likely that if a batch number is known it is also known which batch was the placebo and which was the cell therapy. Certainly a motivated individual could put this information together.

28. If it could be deduced whether the patient received the placebo or the cell therapy this would be revealing personal information about the patient that may not already be known by them, their family or friends. The Commissioner acknowledges the MHRA report footnote states it was later informed a placebo was given but, as the complainant points out, there is some doubt as Celixir's statements conflict with this.

29. Additionally, the Commissioner notes the MHRA report goes on to state:

"To date we have no information that the patient, who was dosed has been informed, and you are required to provide to the MHRA any documents to enable us to confirm that we have correctly identified and contacted the patient"

30. On the basis of the Trust's explanations, the Commissioner will accept that the withheld information falls within the definition of 'personal data' in section 3(2) of the DPA.

31. There is some uncertainty around whether the information is known so the information, if disclosed, relates to the data subject and could reveal personal information about them not otherwise known. While the likelihood of this happening is low, because, as will be discussed below, the information is special category personal data, the Commissioner is satisfied the information should be treated with more caution. This is in line with his 'Anonymisation' code of practice (page 25)

Is the data special category data?

32. Information relating to special category data is given special status in the UK General Data Protection Regulation (GDPR).

33. Article 9 of the UK GDPR defines 'special category' as being personal data which reveals racial, political, religious or philosophical beliefs, or trade union membership, and the genetic data, biometric data for the purpose of uniquely identifying a natural person, data concerning health or data concerning a natural person's sex life or sexual orientation.

34. Having considered the request, the Commissioner finds that the requested information is special category data. He has reached this conclusion on the basis that it concerns the medical/health information of a single individual.

35. Special category data is particularly sensitive and therefore warrants special protection. As stated above, it can only be processed, which includes disclosure in response to an information request, if one of the stringent conditions of Article 9 can be met.

36. The Commissioner considers that the only conditions that could be relevant to a disclosure under FOIA are conditions (a) (explicit consent from the data subjects) or (e) (data made manifestly public by the data subjects) in Article 9.

37. The Commissioner has seen no evidence or indication that the individual concerned have specifically consented to this data being disclosed to the world in response to a FOIA request or that they have deliberately made this data public.

38. As none of the conditions required for processing special category data are satisfied there is no legal basis for its disclosure. Processing this special category data would therefore breach principle (a) and so this information is exempt under section 40(2) of FOIA.

Right of appeal

39. 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: 0203 936 8963
    Fax: 0870 739 5836
    Email: grc@justice.gov.uk
    Website: www.justice.gov.uk/tribunals/general-regulatory-chamber

40. 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.

41. Any Notice of Appeal should be served on the Tribunal within 28 (calendar) days of the date on which this decision notice is sent.

Jill Hulley
Senior Case Officer
Information Commissioner's Office
Wycliffe House
Water Lane
Wilmslow
Cheshire
SK9 5AF