



Ref: FOIA Reference 2021/22-007b

Date: 16th April 2021

Email foi@uhn.nhs.uk

Dear

I am writing in response to your email dated 10th April 2021 (received into our office 12th April) requesting information under the Freedom of Information Act (2000) regarding our response to your request on medical trial.

The University Hospitals of North Midlands Trust is committed to the Freedom of Information Act 2000.

However, the NHS is facing unprecedented challenges relating to the coronavirus (COVID-19) pandemic at the current time. Understandably, our resources have been diverted to support our front-line colleagues who are working tremendously hard to provide care for our patients, and to those in need of our services.

We strive to be transparent and to work with an open culture. But at this time, whilst care of our patients and the safety of our staff takes precedent, it is likely that responses to some requests for information will be delayed. We apologise for this position in advance, and will endeavour to provide you with as much information as we can, as soon as we are able.

The Information Commissioners Office has recognised the current situation in the NHS

You emailed:

'Thank-you for your response. I would like to point out that it is your hospital that recruited the patients, not Keele University. It would therefore be expected that your hospital would be responsible for the ethical conduct of the trial and would have maintained the patient logs. It therefore follows that your hospital is best placed to respond to my FOI request rather than Keele University.

I would also mention that the information I have requested is quite routine, and is the sort of data that hospitals are usually happy to provide'.

On 12th April we acknowledged this query and went back to the division to check our data.

As of 1st November 2014 University Hospitals of North Midlands NHS Trust (UHNM) manages two hospital sites – Royal Stoke University Hospital, and County Hospital (Stafford). Therefore the response below is for the two sites combined from that date where appropriate.

Please see our amended answers below- we apologise for the confusion.

Q1 **My request relates to a trial called IMPROVED. Please see details here:**
<https://clinicaltrials.gov/ct2/show/NCT01891240>

One of the trial sites listed for this this trial is “University Hospital of North Midlands, Stoke-on-Trent, Staffordshire”.

My questions are as follows:

1. Who was the Principal Investigator at your hospital?

A1 This Trial is listed as being conducted by Keele University School of Medicine, therefore this information is not held by UHNM; please contact Keele University School of Medicine at the following email address: medicine@keele.ac.uk

Amended answer:

Professor Shaughn O'Brien

Q2 When was the first patient recruited at your hospital?

A2 As answer 1

Amended answer:

March 2014

Q3 When was the last patient recruited at your hospital?

A3 As answer 1

Amended answer:

July 2016

Q4 How many patients were recruited in total at your hospital?

A4 As answer 1

Amended answer:

529

Q5 How many patients did your hospital initially plan to recruit?

A5 As answer 1

Amended answer:

500

*Please note that any individuals identified do not give consent for their personal data to be processed for the purposes of direct marketing.

UHNM NHS Trust is a public sector body and governed by EU law. FOI requestors should note that any new Trust requirements over the EU threshold will be subject to these regulations and will be advertised for open competition accordingly.

Where the Trust owns the copyright in information provided, you may re-use the information in line with the conditions set out in the Open Government Licence v3 which is available at <http://www.nationalarchives.gov.uk/doc/open-government-licence/version/3/>. Where information was created by third parties, you should contact them directly for permission to re-use the information.

An anonymised copy of this request can be found on the Trust's disclosure log, please note that all requests can be found at the following link: <http://www.uhnm.nhs.uk/aboutus/Statutory-Policies-and-Procedures/Pages/Freedom-of-Information-Disclosure-Log.aspx>

This letter confirms the completion of this request. A log of this request and a copy of this letter will be held by the Trust.

If you have any queries related to the response provided please in the first instance contact my office.

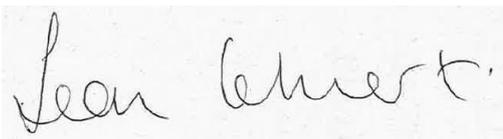
Should you have a complaint about the response or the handling of your request, please also contact my office to request a review of this. If having exhausted the Trust's FOIA complaints process you are still not satisfied, you are entitled to approach the Information Commissioner's Office (ICO) and request an assessment of the manner in which the Trust has managed your request.

The Information Commissioner may be contacted at:

Information Commissioner's Office, Wycliffe House, Water Lane, Wilmslow, Cheshire SK9 5AF or via www.ico.org.uk.

If following review of the responses I can be of any further assistance please contact my secretary on 01782 671612.

Yours,



Jean Lehnert
Data, Security & Protection Manager