



University Hospitals
of North Midlands
NHS Trust

Royal Stoke University Hospital
Data, Security and Protection
Newcastle Road
Stoke-on-Trent
Staffordshire
ST4 6QG

Ref: FOIA Reference 2021/22-138

Date: 7th July 2021

Email foi@uhnm.nhs.uk

Dear

I am writing to acknowledge receipt of your email's dated 4th June 2021 and 17th June 2021 requesting information under the Freedom of Information Act (2000) regarding trial; this is an additional question therefore a new request

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

On 17th June 2021 you emailed an additional question, you stated:

'I would like to alert you to some information I have recently obtained from the HRA concerning [REDACTED] application for ethics approval for the IMPROVED trial. I have attached the application here. In this application, [REDACTED] as the Chief Investigator, is claiming to be the Clinical Director for Obstetrics and Gynaecology at the University Hospital of North Staffordshire (please see p4/31). Even though the name is redacted, it is clear that [REDACTED] is the Chief Investigator because it says on p15/31 section A48 that the Chief Investigator has shares in Diagnostic Metabolomics. I don't think [REDACTED] could have been the Clinical Director for Obstetrics and Gynaecology because he did not have a licence to practise and was working full-time in New Zealand. I appreciate that UHNM might not have been aware of this apparently fraudulent application for ethics approval because the sponsor was Keele University.

Would UHNM care to comment on this? Am I correct in assuming that [REDACTED] was not the Director for Obstetrics and Gynaecology at your hospital?'

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.



Q1 Many thanks indeed for your helpful response (FOI ref 086-2122). I would be most grateful if you could answer a final question concerning the STRIDER trial:

What was the date that the sponsor of the STRIDER trial submitted an amendment to replace [REDACTED] as the Principal Investigator?

A1 Amendment submitted 03 March 2015 (FOI 086-2122).

Q2 You further wrote on 17th June 2021 seeking clarification on whether or not [REDACTED] was employed as Director for Obstetrics and Gynaecology at your hospital at UHNM. Our response to that question is below.

A2 We can confirm that [REDACTED] has never been an employee of UHNM.

*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.

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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.

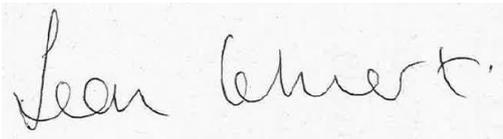
Should you have a complaint about the response or the handling of your request, please also contact my office to request a review of this. If having exhausted the Trust's FOIA complaints process you are still not satisfied, you are entitled to approach the Information Commissioner's Office (ICO) and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

A handwritten signature in black ink on a light-colored background. The signature reads "Jean Lehnert" in a cursive, slightly slanted script.

Jean Lehnert
Data, Security & Protection Manager