



**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 2021/22-553

Date: 25th April 2022

Email foi@uhnm.nhs.uk

Dear

I am writing to acknowledge receipt of your email dated 2nd February 2022 requesting information under the Freedom of Information Act (2000) regarding Medical Device.

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.

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 I would like to request the following information under the Freedom of Information Act in relation to the research I am completing.

Having reviewed your website and policies, I am unable to obtain the relevant documents, which is why I have made this request. I would like to know which documents are used for the review and approval of new medical devices within your NHS Trust/entity.

The exact naming of the documents may differ, but the context is the same, so we ask for judgement to be used, and please let us know if you require further clarification.



Could you please provide a copy of the Trusts/entity “New Medical Device policy?”

A1 UHNM does not have a policy.

Q2 Could you please provide a copy of the Trusts/entity “Medical Devices and Procurement Review Group policy?”

A2 See attached CPEG application form. This is in the process of being updated

Q3 Could you please provide a copy of the Trusts/entity “Business case template for new medical devices or technology” for new medical/diagnostic device approval?

A3 See attached

Q4 Could you please provide a list of all approved medical devices in your Trusts/entity? Excel format, word or PDF is fine.

A4 See attached

Q5 Could you please provide a copy of the policy which supports “medical devices on trial requirements”

A5 See attached

Q6 Could you please provide the policy for including a new pathology test within the Trusts/entity?

A6 We follow the Trust SFI’s (F01) and business planning rules to bring in new tests, All medical devices on trial need to meet the requirements set out within the medical devices policy unless by exception.

Q7 Could you please provide the policy for the “New medical Product Selection Group?”

A7 UHNM does not have a policy for the “New medical Product Selection Group”

Q8 Could you please confirm how often new medical device review meetings take place?

A8 We have a Theatre product evaluation group and a clinical product evaluation group. They meet on alternate months such that there is a meeting on a monthly basis.

Q9 Could you please provide me the name of the staff member responsible for finances of new medical devices and their email address?

A9 The relevant Divisional / Directorate Budget Holder, of which there is no particular named person.

Q10 Could you please provide me the name of the staff member responsible for procurement of new medical devices and their email address?

A10 As answer 9

Q11 Lastly, could you please supply a copy of the last 3 'New Medical Device meeting' minutes and also the location of where they are published on your website?

A11 See attached: Due to COVID surges and the consequent standing down of meetings, they have not been held as regularly as we would like.

Note: Some information within the documents has been redacted. This is because it is exempt under section 40(2) of the FOI Act: *personal information*. The information could be used to identify individuals and therefore has not been released.

*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,



University Hospitals
of North Midlands
NHS Trust

Jean Lehnert
Data, Security & Protection Manager

