

Device Management (MHRA Guidance)

Reference Number: RDF2077-23

Date of Response: 15/12/23

Further to your Freedom of Information Act request, please find the Trust's response(s) below:

Please be aware that the Royal Devon University Healthcare NHS Foundation Trust (Royal Devon) has existed since 1st April 2022 following the integration of the Northern Devon Healthcare NHS Trust (known as Northern Services) and the Royal Devon and Exeter NHS Foundation Trust (known as Eastern Services).

Please can I request the following information under the Freedom of Information Act. Please contact me if you have any questions.

- Please advise what software/systems you use for managing medical devices to be compliant with Medicines & Healthcare products Regulatory Agency (MHRA) Guidance Jan 2021? See link [Safeguarding public health \(publishing.service.gov.uk\)](https://publishing.service.gov.uk)*

Answer: For managing Medical Devices the Trust asset management system is Medusa (provided by SoftPro), this system manages the asset data/servicing information and service contracts.

- If applicable, how long is the contract and when does it expire (month and year)?*

Answer: Annual, expires June 2024.

- What is the annual budget for the system listed in response to question 1?*

Answer: The Trust holds this information. This information is commercially sensitive and its release would, or would be likely to prejudice the commercial interests of the Trust. In applying the exemption under Section 43(2) the Freedom of Information Act the Trust has balanced the public interest in withholding the information against the public interest in disclosure.

The Trust has considered all the relevant factors in the public interest test and concluded that the benefit to the public in applying the exemption outweighs the public interest in releasing the information requested as a result of the prejudices and losses that would potentially affect the Trust and patients. As such this information is being withheld under Section 43 (2). Releasing the costs of contracts would give potential suppliers an unfair advantage over other bidders when bidding for future work. That advantage would contravene the principle of fairness required from the Trust in Regulation 18 of the Public Contracts Regulations 2015. The release of contract values would undermine the Trust's suppliers' competitiveness in the market and breach the Trust's contracts with suppliers, which typically require contract values to be kept confidential.

4. *Please advise on the name and contact for the person responsible for ensuring compliance with the MHRA guidance quoted above.*

Answer: The Trust does not release the names of staff below a Director under Section 40 (2) of the Freedom of Information Act 2000 Personal Information, where disclosure may contravene the Data Protection Act 2018 and therefore applies an exemption under Section 40 (2) - Personal Information of the Freedom of Information Act 2000 and Section 10 of the Data Protection Act 2018.

The Executive Director responsible Zara Hyde – Interim Director of Facilities & Estates. Trust main hospitals sites: 01392 411611 (Eastern services) and 01271 322577 (Northern services) or via the Trust 'Contact Us' link on royaldevon.nhs.uk

Where contact details are given for Trust staff in this response, notice is hereby given, under Section 11 of the Data Protection Act 2018, on behalf of the individual or individuals that this personal information may not be used for the purposes of direct marketing.