Royal Devon University Healthcare NHS Foundation Trust

Covid-19 Booster Informed Consent

Reference Number: F4909
Date of Response: 28/09/2022

Further to your Freedom of Information Act request, please find the Trust's response, in **blue bold text** below:

Royal Devon's Eastern area Response

What steps you and your organisation will be taking to fulfil your ethical and legal obligations to ensure patient and staff submission to Covid vaccination is given with free, voluntary, and fully informed consent.

Note this is inclusive of your patients and staff, not just patients.

The authorisation for vaccines is taken by the Medicines and Healthcare products Regulatory Agency (MRHA). You can find the details here First bivalent COVID-19 booster vaccine approved by UK medicines regulator - GOV.UK (www.gov.uk).

Additional information on the authorisation can be found at Regulatory approval of Spikevax bivalent Original/Omicron booster vaccine - GOV.UK (www.gov.uk)

The NHS takes steps to ensure informed consent across it's immunisation programmes Healthcare professionals start with the assumption that all adults have the capacity to provide consent to their treatment as well as making sure they provide information on the process, the benefits of immunisation, and the risks, including rare and common side effects in accordance with the UK Health Security Agency's (UKHSA) green book, chapter 2 – see Consent: the green book, chapter 2 - GOV.UK (www.gov.uk)