

Reference:	FOI.7993.22
Subject:	Informed consent
Date of Request:	17 January 2022

Requested:

I would be grateful if you could provide the additional information listed below also under the Freedom of Information Act:

1. The Informed Consent form for adults - specifically the one mentioned in your response to me dated 15 July (your Ref CEO.6434)
2. More information on the actual content of the online training for the vaccinators including whether it includes the risk versus benefit analysis and information concerning the adverse effects particularly those which affect particular demographics e.g. young males experiencing pericarditis/myocarditis
3. Whether vaccinators are informed of the laws relating to Informed Consent, including the EU Directive 2001/20/EC and the Universal Declaration on Bioethics and Human Rights
4. The plans Hywel Dda is putting in place to deal with adverse effects, particularly the cardiac related ones

Response:

1. This information is already within the public domain; therefore, Hywel Dda University Health Board (UHB) has applied an exemption under Section 21 of the Freedom of Information Act 2000 (FoIA), as the information is accessible by another means. The UHB has answered a similar Freedom of Information request, FOI.6947.21 - Informed consent provided by Moderna vaccine, which is available on the UHB's disclosure log webpage and can be accessed via the attached links:

FOI.6947.21 - <https://hduhb.nhs.wales/about-us/governance-arrangements/freedom-of-information/disclosure-log/disclosure-logs/informed-consent-provided-by-moderna-vaccine/>

Attachment 1 - <https://hduhb.nhs.wales/about-us/governance-arrangements/freedom-of-information/disclosure-log/disclosure-log-appendices/1-informed-consent-pdf-843kb/>

2. The UHB confirms that a COVID vaccination e-learning course is required to be completed within the Electronic Staff Record (ESR) system as part of a vaccinator's ongoing learning and development. Within this e-learning course, the risk of adverse effects, particularly those which affect demographics e.g. young males experiencing pericarditis/myocarditis is discussed and a link to the Green Book Chapter 14a is incorporated. The Green book also covers 'risk versus benefit' and a link has been provided below:

[COVID-19: the green book, chapter 14a - GOV.UK \(www.gov.uk\)](https://www.gov.uk/government/publications/covid-19-green-book/covid-19-green-book-chapter-14a)

3. The UHB confirms that the COVID vaccination e-learning course covers the laws relating to consent and reference is made to the advice issued by the Nursing and Midwifery Council (NMC), General Medical Council (GMC), General Pharmaceutical Council (GPhC) and Health

and Care Professions Council (HCPC), including the HCPC's Standards of Conduct, Performance and Ethics. However, there is no specific reference within the e-learning course, to the EU Directive 2001/20/EC and the Universal Declaration on Bioethics and Human Rights.

Further information on national immunisation training standards and the courses available to NHS staff, is available on the Public Health Wales (PHW) website and can be accessed via the attached link:

[Training resources available in preparation for the COVID -19 Vaccination - Public Health Wales \(nhs.wales\)](#)

4. The UHB confirms that all adverse vaccine related reactions are reported to the Medicines and Healthcare products Regulatory Agency (MHRA) and recorded on the yellow card scheme. For ease, a link to the website has been provided below:

[Yellow Card Scheme - MHRA](#)

Please note: - Cardiac events following vaccination remain rare.