Reference:	FOI.7120.21
Subject:	Informed consent
Date of Request:	7 October 2021

Requested:

Thank you for responding to my request for information in a letter dated 7 October (FOI 6947). The information provided is helpful.

I note, however, that the "consent template" does not provide information that enables a recipient of the inoculations to make an informed decision on whether benefits outweigh the risk. The following information is not provided.

- 1. Vaccine content.
- 2. Full list of possible adverse reactions [including death]. Your attention is drawn to the latest data from MHRA "yellow card" monitoring system reproduced in Annex 1 below.
- 3. Recipients of the inoculations are not advised that only temporary emergency authorisation has been granted by MHRA, under R174 of Human Medicines Regulations 2012, with Phase 3 trials still ongoing and due to end in 2023.

I would therefore be grateful if you could provide me with contact details [name and email address] of the appropriate senior manager at HDUHB so that these concerns can be further examined in more detail.

Annex 1

Data to 15 September 2021 - from UK Government MHRA "yellow card" reporting system

AstraZeneca - total adverse reactions 825,564 - total deaths 1,072

Moderna - total adverse reactions 51,034 - total deaths 17

Pfizer- total adverse reactions 324,654 - total deaths 534

Unspecified - total adverse reactions 3,292 - total deaths 28

Total - adverse reactions 1,204,544 - total deaths 1,651

It is estimated that, for various reasons, only 10% of serious reactions and between 2 and 4% of non-serious reactions are reported. The information provided above can therefore be adjusted accordingly

Response:

As this information is already within the public domain, 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 confirms that Ros Jervis, Executive Director of Public Health, has overall responsibility for the vaccination programme. Contact details are available on the UHB's website and can be accessed via the attached link:

Board members - Hywel Dda University Health Board (nhs.wales)

Whilst operating in accordance with the Section 45 Freedom of Information Code of Practice, the UHB has a duty to provide advice and assistance.

The UHB has answered a similar Freedom of Information request, FOI/6405/21, that may clarify the information you seek, and is available on our disclosure log.

For ease of reference please click on the attached link, which will take you directly to the UHB's disclosure log webpage:

 $\underline{\text{https://hduhb.nhs.wales/about-us/governance-arrangements/freedom-of-information/disclosure-log/}$