

## **Freedom of Information Act 2000 (FOIA)**

### **Decision notice**

**Date:** 15 April 2025

**Public Authority:** Business Services Organisation

**Address:** 2 Franklin Street  
Belfast  
BT2 8DQ

#### **1. Request:**

The complainant requested the following information from Business Services Organisation on 20 December 2024:

"This is a follow up request to FOI 2277 for which I thank you. I requested (item 2) "Information relating to safety studies of both investigational products in animals, including non-human primates, provided by the sponsor to your committee, prior to approval being granted."

You sent me on 3rd October 2024 copies of the Investigators' Brochure v5 redacted (IB) and the trial protocol, but no actual reports of safety studies in animals.

The IB under section 4.1 (pages 21-24) lists summaries of five preclinical animal studies.

Please would you confirm whether the HSC REC B Ethical Committee holds the results of these animal studies (or only the summaries presented in the IB.)

The reason that I request this is that the vaccine in question has been linked to serious adverse events in young babies, and the trial

has been halted because of this.

Please may you provide me with:

- a) reports of the results of the animal safety studies referred to in the IB, (page 23)  
Particularly "Safety, immunogenicity, and efficacy of mRNA-1345 in the cotton rat RSV model"
- b) correspondence between the Ethics Committee and the Sponsor relating to safety concerns since 1 July 2024.
- c) Copies of "informed consent forms" issued to participants/parents as modified."

## **2. Commissioner's Decision:**

A public authority will breach section 10 of FOIA if it fails to respond to a request within 20 working days. Based on evidence available to the Commissioner, by the date of this notice the public authority has not issued a substantive response to this request. Therefore the Commissioner finds a breach of section 10.

## **3. Steps:**

The public authority must provide a substantive response to the request in accordance with its obligations under FOIA.

The public authority must take this step within 30 calendar days of the date of this decision notice. Failure to comply may result in the Commissioner making written certification of this fact to the High Court pursuant to section 54 of FOIA and may be dealt with as a contempt of court.

## **4. Right of Appeal:**

Either party has the right to appeal against this decision notice to the First-tier Tribunal (Information Rights). Information about the appeals process may be obtained from:

First-tier Tribunal (Information Rights)  
GRC & GRP Tribunals,  
PO Box 9300,  
LEICESTER,  
LE1 8DJ

Tel: 0203 936 8963

Fax: 0870 739 5836

Email: [grc@justice.gov.uk](mailto:grc@justice.gov.uk)

Website: [www.justice.gov.uk/tribunals/general-regulatory-chamber](http://www.justice.gov.uk/tribunals/general-regulatory-chamber)

Any Notice of Appeal should be served on the Tribunal within 28 (calendar) days of the date on which this decision notice is sent.

**Information Commissioner  
Wycliffe House  
Water Lane  
Wilmslow  
Cheshire  
SK9 5AF**