

FOI 23/653

Dear

Thank you for your request of 03 September 2023, under the Freedom of Information Act. You requested:

This request is related to the following study done on the CPRD and led by [name]

Safety of COVID-19 vaccination during pregnancy in England: a cohort study

- Date of Approval : 28-04-2022*
- Application Number : 22_001732*

Would you be able to provide the protocol of the study and the list of expected / available deliverables ?

We confirm that we hold the information you have requested. However, we judge that it is exempt from release. The protocol from this study will be published in the future and we consider that it is exempt under Section 22 (Information intended for future publication) of the Freedom of Information Act. Section 22 of the Act allows public authorities to refuse requests where the authority intends to publish the information at a future date. With regards to deliverables, this study will be published in a peer reviewed journal upon completion.

Section 22 is a qualified exemption and as such we have considered the public interest in withholding the information you have requested. However, we have not identified any overriding public interest arguments that would favour disclosure ahead of the planned publication we have described above.

If you are dissatisfied with the handling of your request, you have the right to ask for an internal review. Internal review requests should be submitted within two months of the date you receive this response and addressed to: info@mhra.gov.uk

Please remember to quote the reference number above in any future communications.

If you were to remain dissatisfied with the outcome of the internal review, you would have the right to apply directly to the Information Commissioner for a decision.

Please bear in mind that the Information Commissioner will not normally review our handling of your request unless you have first contacted us to conduct an internal review. The Information Commissioner can be contacted at:

Information Commissioner's Office
Wycliffe House
Water Lane
Wilmslow
Cheshire
SK9 5AF

Yours sincerely

MHRA Customer Experience Centre

Communications and engagement team

Medicines and Healthcare products Regulatory Agency

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