Freedom of Information Act 2000 (FOIA)

Decision notice

Date: **26 July 2024**

Public Authority: **Health Research Authority (HRA)**
Address: **2 Redman Place, London, E20 1JQ**

Decision (including any steps ordered)

1. The complainant has requested HRA to disclose information relating to the NextCOVE trial. HRA disclosed some information but withheld the remainder under section 43(2) of FOIA.

2. The Commissioner's decision is that section 43(2) of FOIA applies and the public interest rests in maintaining the exemption. He does not require any further action to be taken.

Request and response

3. On 3 December 2023, the complainant wrote to HRA and requested information in the following terms, in relation to the NextCOVE trial (IRAS ID: 1007516):

> "1. The date the sponsor submitted their request for approval of this trial.
>
> 2. Information relating to safety studies of the investigational product in animals, including non-human primates, provided by the sponsor to the REC prior to approval having been granted.
>
> 3. The Trial Protocol, including any specified Adverse Events of Special Interest (AESI).
>
> 4. Details of any modifications to the trial protocol specified by the REC prior to approval.

5. The Investigator's Brochure."

4. HRA responded on 11 December 2023. It disclosed some information but withheld the remainder under sections 43(1) and 43(2) of FOIA.

5. The complainant requested an internal review on 12 December 2023.

6. HRA carried out an internal review and notified the complainant of its findings on 12 January 2024. It upheld its initial position.

Scope of the case

7. The complainant contacted the Commissioner on 2 February 2024 to complain about the way their request for information had been handled.

8. The Commissioner considers that the scope of his investigation is to determine whether or not HRA is entitled to rely on either of the exemptions cited.

Reasons for decision

9. Section 43(2) of FOIA states that information is exempt from disclosure if its disclosure would or would be likely to prejudice the commercial interests of any person (including the public authority holding it).

10. It is also subject to the public interest test.

11. HRA referred the Commissioner to a decision notice he issued on 12 February 2024[1], reference IC-272524-Q8R3, which upheld the application of section 43(2) of FOIA to the exact same withheld information that falls within the scope of this request. It said it remained of the opinion that section 43(2) of FOIA applied to the withheld information for the reasons detailed in this decision notice.

12. The complainant was made aware of this previous decision but considers the wrong decision was made. They made the following submissions to the Commissioner:

"I would like to continue with this complaint as it gives me the right of appeal.

[1] ic-272524-q8r3.pdf (ico.org.uk)

My reasoning is that the previous decision does not fully address the points I made in my complaint.

I suggested in my complaint "The information requested could be redacted to prevent secret or commercially sensitive information being disclosed".

This aspect was not covered in the earlier decision.

I have already sent you an example of one of thousands of trial protocols that have been published with redactions. This is accepted practice.

2) I would like the Commissioner to consider the Public Interest Test in two respects

a) The medical profession is concerned about the lack of access to clinical trial protocols which are seen as important.

"Redactions in clinical trial protocols are an increasing problem and interfere with the ability to accurately appraise and reproduce a clinical trial. There are various reasons for protocol redactions by sponsors, including fears of release of commercially sensitive information or trademarked intellectual property. However, the authors of this study have yet to stumble upon any hidden trade secrets when reviewing many protocols during their research endeavours."

That is a quote from a paper in the British Medical Journal of 14 December 2023. The whole article is attached.

b) There is no need to include trade secrets or commercially sensitive information in a protocol.

In my complaint I explained that a Clinical Trial Protocol is "a full description of your research study. It acts as a manual for the research team at research sites to ensure adherence to the methods outlined"

That definition is taken from the HRA's website:

https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/clinical-trials-investigational-medicinal-products-ctimps/combined-ways-working-pilot/document-management-combined-review-applications/

A Protocol is a practical manual to make sure the trial instructions are carefully followed.

There is no need for trade secrets or commercially sensitive information to be included in such a manual which, as I have pointed out, is widely

distributed to all trial sites. I suggest that it is highly unlikely that highly confidential information would be shared in this way.

I believe it is perverse that the trial Protocol, i.e. a manual/set of instructions, can be rendered exempt from disclosure merely by the Sponsor including trade secrets, or commercially sensitive information, in that document."

13. In a further email the complainant also said:

"I believe this to be important as it refers to a similar problem concerning disclosure of clinical trial protocols, in this instance involving the European Medicines Agency (EMA)

In this case the European Ombudsman ruled in 2010 that trial protocols do not contain commercially confidential information.

"The European ombudsman, P Nikiforos Diamandouros, considered that commercial interests might be at stake but noted that the risk of an interest being undermined must be reasonably foreseeable and not purely hypothetical. He could not see that access would "specifically and actually" undermine commercial interests. He inspected the relevant reports and protocols at the EMA and concluded that the documents did not contain commercially confidential information. He therefore criticised the EMA's refusal to grant [us] access."

I would be grateful if you would forward this email and the attached article (from the British Medical Journal) to the Commissioner."

14. The Commissioner put the complainant's submissions to HRA and also asked it to explain why the period of four months between the two requests (the request here and the request considered in the Commissioner's earlier decision) did not alter its view that section 43(2) applied. HRA was also asked to explain why the withheld information could not be suitably redacted in order to disclose some of the requested information.

15. In terms of the timing of this request, HRA explained that the circumstances had not changed. It referred to the study being ongoing and therefore the reasons for applying the exemption and balancing the public interest remained the same. The Commissioner's earlier decision notice explains these in depth.

16. With regards to redaction, HRA advised that in his earlier decision notice the Commissioner acknowledged that the withheld information is highly technical and accepted that disclosing the information would or could prejudice Moderna's commercial interests.

17. It confirmed that it accepts the need for transparency and to share information which is not exempt wherever possible. It also said it recognises that when providing information, it needs to make sense. HRA stated that if it were to redact the withheld information, it would, for the most part, be the majority of the withheld information. This is because it is commercially sensitive information, which is spread throughout the withheld information, including information regarding:

    • detailed study dose information and immunogenicity information.

    • benefit assessment of the vaccine in comparison with other vaccines.

    • detailed study design information including the scientific rationale for the study and scientific justification for the dose.

    For this reason, HRA confirmed that sharing a redacted version of the documentation is not possible.

18. Addressing the complainant's point of view that there is no need to include commercially sensitive information in a protocol, HRA submitted that whilst guidance may suggest that it need not be within a protocol, in this specific case it is. The withheld information is commercially sensitive in nature and this was accepted by the Commissioner in his earlier decision notice.

19. HRA further stated that it is only able to consider the information requested as it stands; not the general principle of what should or should not be in a protocol.

20. With regards to the complainant's arguments, outlined in paragraph 12 and 13 above, HRA commented that it has revisited the balance of the public interest in light of these and remains of the view that the public interest rests in maintaining the exemption.

21. It noted the complainant's arguments that the medical profession is concerned about a lack of access to protocols which inhibits their ability to appraise and reproduce a clinical trial. HRA advised that this is something which was considered under the earlier request (IC-272524-Q8R3) and as part of this investigation, when the public interest test was considered again in light of the small time difference between the two requests.

22. HRA advised that in response to this point, it supports openness and transparency in relation to research conducted and accepts that publication can support research through peer review.

23. However, it remains HRA and Moderna's view that the ability to reproduce the clinical trial is also a compelling argument in favour of

maintaining the exemption. It commented that the withheld information is commercially sensitive and disclosure would impact the commercial interests of Moderna. While sharing the information with the medical profession would have benefits and support understanding for academics and the wider research community, disclosure under FOIA is not just to this audience but to the world at large. Disclosure would mean competitors of Moderna would have access to the information. It argued that the ability to reproduce the study would undeniably give competitors an advantage and have a significant and real impact on the commercial interests of Moderna.

24. HRA confirmed that as the withheld information is currently not in the public domain, disclosing it could provide potential competitors with an insight into Moderna's product development plans. This would grant them an unfair commercial advantage and could compromise over 10 years of research and development investment into Moderna's platform. It said disclosure could also impact on the commercial viability of the launch of a pipeline of future products.

25. Turning now to the European Ombudsman's ruling in 2010, HRA's response is:

"Whilst the principle should be that trial protocols do not contain commercial sensitive information, in the opinion of the research sponsor, the HRA, and the ICO in its previous review, this protocol does contain information which is commercially sensitive and as such the previous public interest test would apply."

26. HRA has explained how the withheld information remains commercially sensitive in its entirety, why redaction in this specific case is not possible and why reference to other protocols and the 2010 ruling does not alter its position. Each case is considered on its own merits, based on the circumstances at the time of the request and based on the specific contents of the withheld information whether that differs from the norm or not.

27. HRA has addressed the complainant's specific concerns over this earlier decision and outlined why the difference in timing does not alter the application of this exemption or the balance of the public interest test. The Commissioner is satisfied that, in this case, section 43(2) applies and the public interest rests in maintaining this exemption, for the reasons detailed in his earlier decision notice.

Right of appeal

28. 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
    Website: www.justice.gov.uk/tribunals/general-regulatory-chamber

29. If you wish to appeal against a decision notice, you can obtain information on how to appeal along with the relevant forms from the Information Tribunal website.

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

Samantha Coward
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