Gmail

Elizabeth Hart <elizmhart@gmail.com>

HRA response to FOI 2021/FOI/062

FOI <foi@hra.nhs.uk> Wed, Apr 28, 2021 at 11:18 PM
To: "elizmhart@gmail.com" <elizmhart@gmail.com>

Dear Elizabeth,

Freedom of Information (FOI) Act request

We are writing in response to your request for information, under the FOI Act, received on 29 March 2021. Thank you for your enquiry. You requested the following information:

- The information considered by the Research Ethics Committee when reviewing the following study: A phase II study of a candidate COVID-19 vaccine in children (COV006) [COVID-19], REC reference 21/SC/0054

Our response is as follows:

- Please find attached two PDF files containing the information that we can, in accordance with the FOI Act, release. We would ask you to note that personal identifiable information has been redacted in line with the requirements of the Data Protection Act.

- Your request has been refused, in part, under FOIA exemption *section 43 – trade secrets & prejudice to commercial interests*.

- Please note Section 43 is a qualified exemption and as such the public interest must be considered. Whilst the HRA promotes research transparency and recommends the results of all trials be made public, we also note that this study is in its very early stages. Disclosing information at this stage could harm the commercial interests of the Sponsor and Third Parties and breach confidentiality agreements that prohibit the disclosure of such information.

- Some of the documents you have requested contain information relating to a recently developed product and we are of the view that disclosure of the information, which details inside information representing the unique knowledge and know-how of the Chief Investigator, sponsor and the third parties, would prejudice their commercial interests (including intellectual property), giving actual and potential competitors an unfair advantage.

- When handling your request we have considered both the public interest and the interests of the sponsor and other third parties

We hope that this information is helpful to you, but should you require further clarification, please let us know.

If you are unhappy about the way in which your request has been handled, the HRA has an internal complaints procedure through which you can raise any concerns. Further details of this procedure may be obtained by contacting the Complaints Manager via foi@hra.nhs.uk. If you are dissatisfied with the outcome of the complaints procedure, you can apply to the Information Commissioner's Office (ICO), who will consider whether we, as a public authority, have complied with its obligations under the Act, and can require the HRA to remedy any problems. You can find out more about how to do this, and about the Act in general, on their website www.ico.org.uk. Complaints should be sent to:

FOI Complaints Resolution – Information Commissioner's Office

Wycliffe House, Water Lane, Wilmslow, Cheshire SK9 5AF

Kind regards,

Susannah

Freedom of Information

Health Research Authority

HRA | Skipton House, 80 London Road | London | SE1 6LH

T. 0207 972 2487

E. foi@hra.nhs.uk

W. www.hra.nhs.uk

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From: FOI <foi@hra.nhs.uk>
Sent: 31 March 2021 12:16
To: 'elizmhart@gmail.com' <elizmhart@gmail.com>
Subject: Acknowledgement of FOI 2021/FOI/062

Dear Elizabeth,

Freedom of Information (FOI) Act request

Thank you for your email 29 March 2021 requesting the following information:

- The information considered by the Research Ethics Committee when reviewing the following study: A phase II study of a candidate COVID-19 vaccine in children (COV006) [COVID-19], REC reference 21/SC/0054

Your request is being handled under the Freedom of Information (FOI) Act and has been referred to the appropriate personnel for investigation. We will provide you with a response as soon as possible, but no later than 28 April 2020.

Kind regards,

Susannah

Freedom of Information

Health Research Authority

HRA | Skipton House, 80 London Road | London | SE1 6LH

T. 0207 972 2487

E. foi@hra.nhs.uk

W. www.hra.nhs.uk

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From: Elizabeth Hart <elizmhart@gmail.com>
Sent: 29 March 2021 03:15
To: Queries <queries@hra.nhs.uk>
Subject: Re: Re the Oxford-AstraZeneca vaccine trials

Hi, thank you for your response.

You provided a hyperlink to the Research Summary for REC reference 21/SC/0054: https://www.hra.nhs.uk/planning-and-improving-research/application-summaries/research-summaries/a-phase-ii-study-of-a-candidate-covid-19-vaccine-in-children-cov006-covid-19/

I presume the South Central - Berkshire Research Ethics Committee, considered more information than just this research summary?

Is all the information considered by the Ethics Committee accessible to the public?

Can you provide me with access to this information?

I would appreciate your early response on this matter, as there are suggestions the Covid vaccine could be rolled out to children by autumn.

Kind regards

Elizabeth Hart

On Sat, Feb 27, 2021 at 1:36 AM Queries <queries@hra.nhs.uk> wrote:

> ## ENQUIRY TO QUERIES LINE
>
> Dear Elizabeth,

Thank you for contacting the Health Research Authority in relation to your enquiry about the inclusion of children in COVID-19 vaccine trials. The Health Research Authority is responsible for the management of Research Ethics Committees (RECs) in England.

In your email you have referred to an interview with Professor Andrew Pollard in which Professor Pollard had stated that the Oxford-AstraZeneca vaccine would begin to be tested in different age groups, including children. At the time this interview was published a COVID-19 vaccine study in children had not yet been reviewed by a REC however, on 12th February the trial received a favourable ethical opinion.

In terms of the ethics review, The Medicines for Human Use (Clinical Trials) Regulations 2004 provide specific conditions and a series of principles relating to the inclusion of children in Clinical Trials of Investigational Medicinal Products (CTIMPs). Our Research Ethics Committees consider whether these principles and conditions have been adhered to when reviewing new research protocols.

When reviewing CTIMPs involving children, RECs will need to consider the potential risks to the population group whilst also ensuring that there are still opportunities for children and young people to access treatments which could potentially be beneficial, as well as addressing the potential risk of not advancing therapies in children. RECs will consider whether the researchers have undertaken a robust assessment of the benefits, harms and burden to children and their families.

The research summary for the trial to investigate a COVID-19 vaccine in children and adolescents provides the following rationale for the inclusion of children in the trial:

'Immunising children is likely to be an important step in gaining control of the pandemic in the UK, as teenagers have some of the highest swab positivity rates in the UK as of December 2020, and immunising school-age children is important to protect vulnerable adults e.g. teachers and carers. This study will give us valuable information on safety aspects of the vaccine and its ability to generate good immune responses against the virus in this age group. In total we will enrol 300 participants between the ages of 6 and 17 years of age'.

I hope the above information is helpful and please do not hesitate to contact me if I can provide any further information

Regards,

Queries Line
REF 48/15/114/81

The Queries Line is an email-based service that provides advice from HRA senior management, including operations managers based in our regional offices throughout England. Providing your query in an email helps us to quickly direct your enquiry to the most appropriate member of our team who can provide you with an accurate written response. It also enables us to monitor the quality and timeliness of the advice given by the HRA to ensure we can give you the best service possible, as well as use queries to continue to improve and to develop our processes.

Health Research Authority

2 Redman Place | Stratford | London | E20 1JQ

E. queries@hra.nhs.uk
W. www.hra.nhs.uk

From: Elizabeth Hart <elizmhart@gmail.com>
Sent: 09 February 2021 11:46
To: Berkshire <berkshire.rec@hra.nhs.uk>
Subject: Re the Oxford-AstraZeneca vaccine trials

For the attention of:
Mr David Carpenter
Chair, Berkshire Research Ethics Committee

Dear Mr Carpenter

Re the Oxford-AstraZeneca vaccine trials

I understand the Berkshire Ethics Committee evaluates the protocols for the Oxford-AstraZeneca vaccine trials, is this correct?

If so, I hope you will consider my query below and provide a response.

In an interview on The BMJ, Professor Andrew Pollard, lead investigator of the trials, said **"we're moving on to new trials to evaluate different age groups, for example, children".** (See: How the Oxford-AstraZeneca covid-19 vaccine was made: https://www.bmj.com/content/372/bmj.n86

I'm questioning the justification for including children in coronavirus vaccine trials.

Young people are generally not at serious risk with the SARS-CoV-2 virus.

To vaccinate people at an early age with what potentially could be annual coronavirus vaccination throughout life, with unknown long-term cumulative consequences, raises important ethical questions, particularly when they are not at serious risk of disease.

The Helsinki Declaration states: **"Medical research involving human subjects may only be conducted if the importance of the objective outweighs the risks and burdens to the research subjects."**

As children appear to not be at serious risk with SARS-CoV-2, in my opinion the risks and burdens for them participating in vaccine trials outweigh the importance of the objective of the medical research, particularly as the plan is for children in general society to be vaccinated, when this appears to not be appropriate.

Mr Carpenter, **on what basis did the ethics committee evaluating the protocols for the Oxford-AstraZeneca vaccine trials conclude it was justifiable to include children and others not at serious risk of the SARS-CoV-2 virus?**

My questions have also been published as a rapid response on The BMJ, see: Is it ethical to include children in the Oxford-AstraZeneca vaccine trials:
https://www.bmj.com/content/372/bmj.n86/rr-2

I would appreciate your response on this matter.

Sincerely
Elizabeth Hart
Independent person investigating the over-use of vaccine products and conflicts of interest in vaccination policy

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2 attachments

Portfolio1.pdf
16227K

Portfolio amend5.pdf
4332K