

Date: **8 May 2019**

Our reference: **FOIRQ5170**

Dear Sir/Madam,

Thank you for your request for information processed under the Freedom of Information Act 2000. Please see our response to your request below:

Your Request

1. Could you kindly provide me with any documentation or communications that shed light on the decision not to re-submit the proposal to REC1 but instead to submit it to REC2? (eg did the researchers appeal the decision?) REC1 communicated their unfavourable opinion to the Institute of Child Health on 6 September 2010 and the Institute re-submitted its research proposal on 4 November 2010, so any search for emails would only need to cover the brief period of time between these two dates.

2. Could you please share with me a copy of the covering letter sent with the revised proposal in November 2010, that explains how the researchers had taken the concerns of REC1 into account?

3. The research study was designed to last for 6 years and an interim report would be produced at the halfway point. But in or around 2014, the study was extended indefinitely. Could you please share with me any data that would clinically justify the decision to extend the trial? REC Standard Operating Procedures state that there is no need to seek the REC's approval for a time extension but "annual progress reports should continue to be submitted... giving reasons for the extra time needed to complete the research."

It is necessary for RECs to be kept informed of the progress of research they have approved, via an annual progress report. Would you kindly share with me these annual progress reports?

Our Response

Great Ormond Street Hospital for Children NHS Foundation Trust (the 'Trust') did not take part in this study. UCL's Institute of Child Health (ICH) was the organisation responsible for the conduct and management of this research study. The Trust has made some enquiries to where you should re-direct your request for information. We have been advised that you should contact Professor Viner in the first instance; whose contact details are accessible on UCL's website link at: <https://www.ucl.ac.uk/child-health/people/viner-russell>

Please note:

The information provided under the Freedom of Information Act 2000 is the information held on the date the request was received by the Trust.

I trust the information provided is sufficient and helps to answer any concerns, questions or issues you may have.

If you should have any further queries related to this request, please do not hesitate to contact the FOI Team. Please ensure that the above reference number is quoted on any correspondence.

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Yours sincerely

Freedom of Information team

Great Ormond Street Hospital for Children NHS Foundation Trust

Email: foiteam@gosh.nhs.uk

[Enclosed – Your rights – see next page]

Your Rights

If you are not dissatisfied with the response you have received to your request for information, please contact the FOI team and quote your reference number on all correspondence relating to your request.

You can also write to the Head of Quality & Safety at the following address:

Quality & Safety team
Great Ormond Street Hospital
LONDON
WC1N 3JH

If you are still not satisfied with your response, you also have the right to appeal to the Information Commissioner.

You can contact the Information Commissioner's Office at the following address:

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