

## Freedom of Information Act 2000 disclosure log entry

### Reference

19-20110 – (refers to FOI case ref: 19-20011)

### Date sent

26/07/2019

### Subject

GIDS Research Information (2)

### Details of enquiry

Could I kindly ask the Trust to check one of its answers to my [previous] FOI request? question 4 [FOI, Case Ref: 19-20011 GIDS Research Information].

1. is it the case that the researchers did not appeal the REF1 decision? For it is apparent from the REC Standard Operating Procedures in effect at the time (v.4.1) that "to seek an opinion from another REC" was, actually, to appeal the unfavourable opinion
2. If it turns out that the Trust did, in fact, appeal the REC1 unfavourable opinion, then there will be a written notice of appeal somewhere, that was sent to the appeals manager who in this instance was Head of Operations at the National Research Ethics Service, based at Darlington

#### **Previously submitted Q 4 Q&A from FOI 19-20011 GIDS Research Information**

4. If the research proposal was re-submitted to REF2 because the researchers had appealed against REF1's decision, could you please state this?

There was no appeal against the decision made by REF1.

The options after an unfavourable opinion are to submit again to the original REC or to seek an opinion from another REC, providing all information from the first application. The investigators concluded that a REC with greater experience of dealing with rare conditions in children would better understand the issues, and elected to submit a revised application to REC 2.

We wrote to the REC2 Chair outlining our responses to the decision by REC1 and why we believed that this was in error. REC2 were supplied with our original application to REC1, their decision letter and our response

#### **Results of research study 10/H0713/79**

In the application (section A13), the researchers stated that "at the end of the first three years the data will be analysed and an interim report will be produced giving a provisional evaluation in line with the objectives of the study. The final report will be produced at the end of the 6 years." The Trust published a news story on its website on 6 April 2011 stating that "The study has a robust system of outcome monitoring."

### Response Sent

We have shared with you the information we hold on our applications to both REC1 and REC2 in relation to our Early Intervention Study, including relevant correspondence. The process was followed as we understood it and no concerns were raised with us at the time by either REC about the process we followed. It was clear in our letter to REC2 the reasons REC1 gave an unfavourable opinion and we addressed these in turn. As we have previously stated, we did not make a formal appeal about the REC1 decision