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From THE DEAN

PROFESSOR ARSHI ZUCKERMAN, MD, DSc, FRCP, FRCPed

27th July 1998

Professor Sir David Hull,

Dear Sir David,

I am now able to respond to your letter of 6th July 1998 concerning the investigation of children with pervasive development disorder for bowel disorder at the Royal Free.

The original protocol was approved by the Ethics Committee of the Royal Free Hampstead NHS Trust and the Medical School on 13th November 1997. The Committee was very conscious of the requirement to avoid non-therapeutic research of more than minimal risk in young children. Assurance was therefore sought and obtained that the investigations that were to be carried out during this study were indicated clinically and were not being carried out just for research. The study was undertaken with parental consent.

Subsequently, children have been seen by clinicians and are investigated by clinical need. The tests which are usually carried out include a range of blood tests, plain X-ray of the abdomen and ileo-colonoscopy with appropriate biopsies. A review by a child psychiatrist is also undertaken.

As an outcome, most of the children have been found to have non-specific colitis with lymphoid hyperplasia and have been started on treatment with Mesalazine or related drugs, generally with a favourable clinical response. The results will be analysed in due course.

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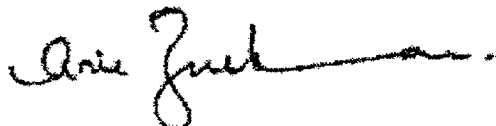
Professor Sir David Hull
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I referred your letter to the Ethics Committee, and the senior clinician responsible for the care of these children wrote formally to the Chairman of the Ethics Committee requesting approval by the Committee for clinical research analysis of the children with this syndrome who are seen by clinical need. The Chairman of the Ethics Committee wrote to me on 24th July 1998 that the study was reviewed again by the Committee on 22nd July 1998. Reassurance was given that only investigations which were indicated clinically would be carried out. Again the Committee approved the study on "Autism and non-specific colitis and nodular hyperplasia" on the understanding that all that was being approved was data collection.

The Chairman of the Ethics Committee also wrote to me pointing out that your comment that: "I see that the investigations were approved by the Ethical Practices Committee of the Royal Free Hospital NHS Trust" was incorrect. He adds that the Committee did not approve the investigations. The Committee approved data collection from investigations that were indicated clinically and that it is not the role of an Ethics Committee to question clinicians' judgement as to what are and what are not clinically indicated investigations. The Chairman of the Committee added that the Committee seeks expert review of all applications, and in the case of this particular investigation the opinion of a senior gastroenterologist was sought and a review of the project was provided with strong support of the study.

Please let me know if you require further information.

Yours sincerely,



Professor A.J. Zuckerman
Dean and Professor of Medical Microbiology

c.c. Mr Martin Else, Chief Executive of the Royal Free Hampstead NHS Trust
Mr Adam Lewis, Medical Director of the Royal Free Hampstead NHS Trust
Professor Sir John Pattison, Vice-Provost and Dean, UCL Medical School
Professor John Walker-Smith, Paediatric Gastroenterology
Professor Leon Fine, University Department of Medicine
Professor Roy Pounder, University Department of Medicine