

Extension: 5628

ROYAL FREE HOSPITAL & MEDICAL SCHOOL
ETHICS COMMITTEE

c/o Maureen Carrol,
Administration Corridor

24th July 1998

Professor A. Zuckerman,
Dean,
RFHMS.

PRIVATE & CONFIDENTIAL

Dear Professor Zuckerman

**Re: 172-96 A new paediatric syndrome: Enteritis and disintegrative disorder
following measles/rubella vaccination**

The above application was first considered at the ethics committee meeting on 13/11/96. The committee was very conscious of the requirement to avoid non-therapeutic research of more than minimal risk in young children. We therefore asked for reassurance that the investigations that were to be carried out in this study were clinically indicated and were not being carried out just for research. Professor Walker-Smith gave me that written reassurance:

"I can confirm that children would have these investigations even if there were no trial"

Thus at the ethics meeting in December there was no real ethical issue to address. The children were having the investigations as part of normal clinical practice and the ethics committee was involved purely because the cases were being collected for report by publication. The study was therefore approved.

On 22/7/98 the ethics committee reviewed this study again following a report by Professor Walker-Smith. The study was now titled "Autism and Non-Specific Colitis and Lymphoid Nodular Hyperplasia". Again Prof. Walker-Smith gave us reassurance that only clinically indicated investigations would be carried out:

"I would like formally to request Ethical Committee approval for our clinical research analysis of these children who we are continuing to see by clinical need".

Again the ethics committee approved the study on the understanding that all that was being approved was data collection.

On 9th July you wrote to me for my comment on the letter of Professor David Hull. In his letter Professor Hull states:

"I see that the investigations were approved by the Ethical Practices Committee of the Royal Free Hospital NHS Trust"

This is, of course, incorrect. We did not approve the investigations. We approved data collection from clinically indicated investigations. It is not, at present, the role of an ethics committee to question clinicians judgement as to what are and what are not clinically indicated investigations. However we do not just take the word of the investigator, rather we ask for independent expert review of all applications. In this case Dr Owen Epstein provided a review of the project and I have a letter from him "strongly supporting" the study.

I hope I have answered all your questions regarding the ethical review of this study.

Yours sincerely,

Dr Michael S. Pegg
Chairman, Ethics Committee