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UNIVERSITY DEPARTMENT OF PAEDIATRIC GASTROENTEROLOGY

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11 November 1996

Royal Free Hospital

Dr Michael S. Pegg Chairman, Ethics Committee Department of Anaesthesia RFH

Dear Dr Pegg

Re: Ethical Committee submission 172-96

Many thanks for your letter.

1. Despite extensive enquries we could not find what ARSAC means.

- 2 Clearly this is an intensive regime with procedures that could be regarded as "high" risk although they are particularly used for the investigation of children with chronic inflammatory bowel disease. These children suffer from a disease with a "hopeless prognosis" in relation to their corebral disintegrative disorder. They have often not had the level of investigation which we would regard as adequate for a child presenting with such a devastating condition. In relation to their gastrointestinal symptoms which will be present in all the children we investigate, these have often been under-investigated. We have so far investigated 5 such children on a clinical need basis, all in fact have proved to have evidence of chronic bowel inflammation. One child has already had a significant response to enteral feeding. Certainly there is a measurable benefit to the child:
  - 8) Establishing a diagnosis and excluding metabolic and other causes
  - b) Commencing on a therapeutic regime

This whole study is parent/patient driven as every case referred has been initiated by the GP by the parents of the child.

I can confirm that children would have these investigations even if there were no trial. I must make clear that we would not be investigating children without gastrointestinal symptoms.

We agree that consent always involves discussion and signature of the researcher. We will change the protocol.

With Kind Regards

Yours sincerely.

J.A. Walker-Smith

Professor of Paediatric Gastroenterology

CC: Dr Andy Wakefield

Dr Simon March