

A statement by The Royal Free and University College Medical School and The Royal Free Hampstead NHS Trust

We are entirely satisfied that the investigations performed on the children reported in the *Lancet* paper had been subjected to appropriate and rigorous ethical scrutiny. Because the nature of the condition affecting child behaviour and gastroenterological symptoms was unknown and required elucidation, the investigation of these children was properly submitted to and fully discussed by the Ethical Practices Committee at the Royal Free Hampstead in 1996. Specifically, that committee was a sub-committee of the then Camden and Islington Health Authority Research Ethics Committee (subsequently incorporated into the new Central Office for Research Ethics Committee arrangements) whose decisions were independent of the university and hospital. The committee, after clarifying a number of issues including that the children's investigations were defined by the clinical symptomatology and diagnostic requirements, and having taken expert advice, approved the protocol submitted.

The clinical management and investigation of these children was performed at the Free by a dedicated team of consultant paediatric gastroenterologists, in full consultation with and agreement of the parents of the affected children. The investigations were those thought appropriate in the light of the severity of the children's symptoms according to the clinician's judgment at the time.

Had the advice of the Institutions been sought at the time concerning conflict of interest, they would undoubtedly have advised that any potential conflict should be declared, so that others could judge whether such conflicts were real.

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