

Mrs Drs. J. Escher
Department of Pediatric Gastroenterology
Room SP 3462
Erasmus MC-Sophia Children's Hospital

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Ons kenmerk HKM/ss/024713
Datum 16 mei 2007

Betreft No objection amendment MEC-2004-108

Postadres

Postbus 2040
3000 CA Rotterdam

Dear Mrs Escher,

Bezoekadres

's Gravendijkwal 230
3015 CE Rotterdam

The Medical Ethics Committee Erasmus MC (i.e. Institutional Review Board of the University Medical Center Rotterdam) in Rotterdam, The Netherlands, acknowledges the receipt of your letter d.d. 10 april 2006 and a amendment regarding the research proposal: 'ESPGHAN Paediatric IBD Porto Criteria Registry', MEC 2004-108.

Parkeergarage
Dr. Molewaterplein 40
3015 GD Rotterdam

We have discussed the amendment in the meeting of the daily board committee on 24 april 2007.

Voorzitters

Prof.dr. H.W. Tilanus
Prof.dr. J.W. Wladimiroff

The amendment concerns no more than filling in a webbased system for each new IBD patient. The data recorded are anonymised and will be used only to record the work-up and some disease characteristics in every new patient. Since no patients are subjected to a treatment or are required to behave in a certain manner, this proposal does not require a full review by the Medical Ethics Committee according to the WMO (Medical Research Involving Human Subjects Act).

Vice-voorzitters

Dr. A. Beishuizen
Dr. F.A.L.M. Eskens

Therefore, the Committee only has checked to proposal in terms of completeness and the protection of the privacy of the participating subjects. The processing of personal data is also regulated by the *Personal Data Protection Act (Wbp)*.

Secretarissen

Mw. mr. C.P. Bron-
van Vliet
Mw. mr. H.I. Kernkamp-
Maathuis
Mw.drs. R.M.M. Bosschaart-
Castermans

I hereby declare, on behalf of the Medical Ethics Committee, that the committee has no objection to the amendment.

Procedure-coördinator

Mw. E. de Zwart

Sincerely,

Secretaresses

Mw. G.J. Slag
Mw. S. Sneevliet

On behalf of the Medical Ethics Committee of Erasmus MC

Het secretariaat is
geopend van maandag
tot en met donderdag
van 08.30 tot 17.00 uur

Mw.mr. H.I. Kernkamp-Maathuis
Secretary