



National Research Ethics Service

Northern & Yorkshire REC

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30 December 2009

Dr John D Grainger
Consultant Paediatric Haematologist
Royal Manchester Children's Hospital
Pendlebury
Manchester
M27 4HA

Dear Dr Grainger

Study title: United Kingdom Paediatric Chronic ITP Registry
REC reference: 06/MRE03/9
Amendment number: Substantial Amendment No 1 7/11/2009
Amendment date: 27 November 2009 (Amendment Form)

The above amendment was reviewed at a meeting of the Sub-Committee held on 30 December 2009.

Ethical opinion

The members of the Committee taking part in the review gave a **favourable ethical opinion** of the amendment on the basis described in the notice of amendment form and supporting documentation.

Approved documents

The documents reviewed and approved at the meeting were:

Document	Version	Date
Covering Letter	Letter from Dr John Grainger	28 November 2009
Notice of Substantial Amendment (non-CTIMPs)	Notice of Substantial Amendment form	27 November 2009
Protocol	V2 -tracked changes	07 November 2009

Membership of the Committee

The members of the Committee who took part in the review are listed on the attached sheet.

R&D approval

This Research Ethics Committee is an advisory committee to North East Strategic Health Authority
The National Research Ethics Service (NRES) represents the NRES Directorate within the National Patient Safety Agency and Research Ethics Committees in England

All investigators and research collaborators in the NHS should notify the R&D office for the relevant NHS care organisation of this amendment and check whether it affects R&D approval of the research.

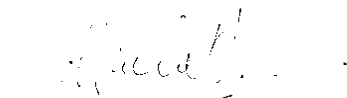
Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees (July 2001) and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

06/MRE03/9:

Please quote this number on all correspondence

Yours sincerely



Mr Bill Hackett
Committee Co-ordinator

E-mail: bill.hackett@suntpct.nhs.uk

Enclosures: List of names and professions of members who took part in the review

Northern & Yorkshire REC

Attendance at Sub-Committee of the REC meeting on 30 December 2009

<i>Name</i>	<i>Profession</i>	<i>Capacity</i>
Dr Peter Carey	Consultant Haematologist	Expert
Mr Michael Davidson	Lay Member	Lay
Mrs Janet Hattle	Head of Pharmacy	Expert
Dr Deborah Hepworth	Senior Lecturer in Research	Expert