Northern and Yorkshire Multi-Centre
Research Ethics Committee

Northern & Yorkshire MREC
Sunderland Teaching Primary Care Trust (South Office)
Admin Corridor
Ryhope Hospital, Ryhope
Sunderland
SR2 0LY

Telephone: 0191 5699561
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22 March 2006

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

Dear Dr Grainger

Full title of study: **United Kingdom Paediatric Chronic ITP Registry**
REC reference number: **06/MRE03/9**

The Research Ethics Committee reviewed the above application at the meeting held on 10 March 2006.

Ethical opinion

1 The Committee accepted assurances provided by the researcher that a re-consenting process would occur when children had the capacity to understand what was required of them.
2 The Committee noted that information sheets were included in the protocol for parents, children aged 8 years of age, children aged 14 - 16 years of age, all of which were of a satisfactory standard.
3 It is suggested that the researcher should develop an information sheet for children aged 10 - 12 years of age rather than just having one for those aged 8 - 14 years.
4 Indemnity arrangements should be "applicable" and this needs to be noted and changed.
5 Details of the secondary outcome measure for parents and older children needs to be included in the information sheet in a 'friendly' language. The secondary outcome being that individuals may be approached regarding other studies.
6 The Committee felt that the GP letter was an 'information' letter which needed rewording to invite clinicians to participate in the study which would involve them in data collection.
7 The Committee felt that changes should be made to the "yes/no" boxes on the consent form to indicate that participants should initial these.
8 The participant information sheet needs amending so that versions and dates conform.
9 Some doubt was expressed whether the invitation letter to parents was required at all, given that this is covered in the patient information sheet.

Agreed -

The Committee agreed to grant a final favourable opinion for this study provided the researcher accepted and implemented the aforementioned advice.

The members of the Committee present gave a favourable ethical opinion of the above research on the basis described in the application form, protocol and supporting documentation.

Ethical review of research sites

The Committee agreed that all sites in this study should be exempt from site-specific assessment (SSA). There is no need to complete Part C of the application form or to inform Local Research Ethics Committees (LRECs) about the research. The favourable opinion for the study applies to all sites involved in the research.

Conditions of approval

The favourable opinion is given provided that you comply with the conditions set out in the attached document. You are advised to study the conditions carefully.

Approved documents

The documents reviewed and approved at the meeting were:

Document	*Version*	*Date*
Application		14 February 2006
Investigator CV	John David Grainger	
Protocol	1	11 October 2005
Covering Letter	1	08 February 2006
Questionnaire Initial Registration	1	08 February 2006
Questionnaire 6 Month Follow up	1	08 February 2006
Questionnaire 12 Month follow up	1	08 February 2006
Questionnaire Yearly Follow up	1	08 February 2006
Questionnaire Pre operative therapy registry	1	08 February 2006
Questionnaire Splenectomy registry	1	08 February 2006
Questionnaire severe Bleed	1	08 February 2006
Questionnaire Outcome	1	08 February 2006
Letter of invitation to participant	1	08 February 2006
GP/Consultant Information Sheets	1	08 February 2006
Letter from ITP Support Ass		25 September 2005
letter from R&D Royal Manchester Childrens Hospital		11 July 2005
Letter from ICIC Steering Committee re statistical overview		03 October 2005
Letter of support from The Paediatric Haematology Forum		
Synopsis	1	08 February 2006

Research governance approval

You should arrange for the R&D Department at all relevant NHS care organisations to be notified that the research will be taking place, and provide a copy of the REC application, the protocol and this letter.

All researchers and research collaborators who will be participating in the research at a NHS site must obtain final research governance approval before commencing any research procedures.

Where a substantive contract is not held with the care organisation, it may be necessary for an honorary contract to be issued before approval for the research can be given.

Membership of the Committee

The members of the Ethics Committee who were present at the meeting are listed on the attached sheet.

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**

With the Committee's best wishes for the success of this project.

Yours sincerely

Dr Fiona Douglas
Chair

Email: Helen.Wilson@suntpct.nhs.uk

Enclosures: *List of names and professions of members who were present at the meeting and those who submitted written comments*

Standard approval conditions

Copy to: *Andrea Evans*
Research & Development Directorate
Room G26
Giving for Living Postgraduate Centre
Royal Manchester Children's Hospital
Manchester
M27 4HA

Northern & Yorkshire MREC

Attendance at Committee meeting on 10 March 2006

Committee Members:

Name	*Profession*	*Present?*	*Notes*
Dr Fiona Douglas	Consultant Clinical Geneticist	Yes	
Dr Peter Carey	Consultant Haematologist	No	
Mr Michael Davidson	N/A	Yes	
Mr Babatunde Gbolade	Consultant Gynaecologist	No	
Dr Janine Gray	Statistician	No	
Dr Deborah Hepworth	Senior Lecturer in Research	No	
Dr John Keeler	Consultant Anaesthetist	No	
Mrs Liz Mellor	Clinical Governance Lead Pharmacist	Yes	
Mr John Martinez	N/A	Yes	
Mr Iain Smith	Senior Lecturer in Health Services Research	No	
Mrs Madeleine Wang	N/A	Yes	
Dr John Newton	Social Scientist	Yes	
Dr Brian Lunn	Psychiatrist	Yes	
Mr Malcolm Khan		Yes	
Ms Dena Cohen		Yes	
Dr Jane Lothian	GP	No	

Also in attendance:

Name	*Position (or reason for attending)*		
Mr Bill Hackett	Ethics Co-ordinator	Yes	
Mrs Helen Wilson	Assistant Ethics Co-ordinator	Yes	

Dear Dr Grainger

Thank you for your email.

I can confirm that we received your letter on 11 April 2006 outlining the amendments you have made to the documents. These were sent to the Chairman for information only as this study received a final favourable opinion on 22 March 2006. You can now proceed with the study as everything is in order.

Regards.
Helen

-----Original Message-----
From: Grainger John (RW3) CM&MC Manchester [mailto:John.Grainger@CMMC.nhs.uk]
Sent: 09 May 2006 11:01
To: Wilson Helen (5KL) Sunderland TPCT
Subject: 06/MRE03/9[Scanned]
Sensitivity: Confidential

UK Paediatric Chronic ITP registry
06/MRE03/9

Dear Dr Douglas,
In response to the committee request for further information sheet for the above study and other minor amendments these were submitted back to the committee mid-April. Please can you clarify that these are fine and that we can now proceed with recruitment or whether the amendment are still under review. Please feel free to phone or email me to discuss further at the contact details below.
Regards
John Grainger

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