



# Health Research Authority

## NRES Committee North East - York

Jarrow Business Centre  
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Tel: 0191 428 3476

15 September 2015

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 2 - 10/6/15  
**Amendment date:** 10 June 2015

The above amendment was reviewed by the Sub-Committee in correspondence.

### Summary of Amendment

This amendment was to change the inclusion criteria so that patients diagnosed longer than 12 months ago could be added to the registry.

### 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.

The Sub-committee reviewed the amendment and raised the following queries:

1. The PIS should be more specific about the identifiable data to be collected. The removal of wording stating that anonymised data is sent to central data manager as in section 8 of the PIS it states that a unique case number would be used to identify the participants and they will not be identifiable.
2. Sections of the PIS should be reviewed for consistency and should include explicitly that the information includes potentially identifiable data (initials, date of birth, postcode and email address) and explain why this is needed and how this information would be safeguarded.
3. It was requested that more information about the process as to how existing participants would be re-consented, particularly how a potentially sensitive issue would be handled that previously collected date of birth and postcode whilst referring to this as anonymised data. What action would be taken if participants do not wish to consent?
4. Please note that P9 Paragraph 2 of the Protocol states that anonymous data is to be collected.

*The applicant responded with an updated Protocol.*

The Sub-Committee were happy with the changes made and approved the amendment.

### **Approved documents**

The documents reviewed and approved at the meeting were:

<i>Document</i>	<i>Version</i>	<i>Date</i>
Covering letter on headed paper	Email from Stephanie Farrell	14 August 2015
Notice of Substantial Amendment (non-CTIMP)	Substantial Amendment 2 - 10/6/15	10 June 2015
Other [Details of Changes to the Protocol]		
Research protocol or project proposal	Version 3	10 June 2015
Research protocol or project proposal	3, tracked change	10 September 2015

### **Membership of the Committee**

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

### **R&D approval**

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 and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

We are pleased to welcome researchers and R & D staff at our NRES committee members' training days – see details at <http://www.hra.nhs.uk/hra-training/>

<b>06/MRE03/9:</b>	<b>Please quote this number on all correspondence</b>
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Yours sincerely  
Pp



**Dr Giles McCracken**  
**Chair**

E-mail: [nrescommittee.northeast-york@nhs.net](mailto:nrescommittee.northeast-york@nhs.net)

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

## NRES Committee North East - York

### Attendance at Sub-Committee of the REC meeting in correspondence

#### Committee Members:

<i>Name</i>	<i>Profession</i>	<i>Present</i>
Mr Steve Chandler	Retired Consultant Medical Physicist	Yes
Dr Giles McCracken (Chair)	Senior Clinical Lecturer	Yes

#### Also in attendance:

<i>Name</i>	<i>Position (or reason for attending)</i>
Miss Donna Bennett	REC Assistant