



Health Research Authority
NRES Committee Yorkshire & The Humber - Leeds West

Room 001, Jarrow Business Centre
Rolling Mill Road
Jarrow
Tyne and Wear
NE32 3DT

Tel: 0191 428 3444

02 September 2015

Mr Alex Smith
Senior Research Fellow
Epidemiology & Cancer Statistics Group
Department of Health Sciences
Faculty of Science
Seebohm Rowntree Building Area 3
University of York
York
YO10 5DD

Dear Mr Smith

Study title: Yorkshire and Humberside Haematology Network Register
REC reference: 04/Q1205/69
Amendment number: Substantial Amendment 13
Amendment date: 10 August 2015

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

Summary of amendment

This amendment was submitted to inform the Committee of changes to the consent form and the Participant Information Sheet to provide information to the participant that their information may be shared with the Health and Social Care Information Centre and other central UK NHS organisations and that consent would be sought for this.

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 requested that reference to 'you' be amended to refer to 'your child' within the Parents Leaflet.

You responded on 02 September 2015 with an updated Information Sheet.

The Sub-Committee was happy with the changes made.

Approved documents

The documents reviewed and approved at the meeting were:

<i>Document</i>	<i>Version</i>	<i>Date</i>
Notice of Substantial Amendment (non-CTIMP)	Substantial Amendment 13	10 August 2015
Participant consent form [Adult Consent Form]	10	10 August 2015
Participant consent form [Older Children Consent Form]	4	10 August 2015
Participant consent form [Younger Children Consent]	4	10 August 2015
Participant information sheet (PIS) [Adult Information Sheet]	10	10 August 2015
Participant information sheet (PIS) [Older Children Information Sheet]	4	10 August 2015
Participant information sheet (PIS) [Younger Children Leaflet]	4	10 August 2015
Participant information sheet (PIS) [Parents Information Sheet - amended]	4	10 August 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/>

04/Q1205/69:	Please quote this number on all correspondence
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Yours sincerely
pp



Dr Vera Neumann
Vice-Chair

E-mail: nrescommittee.yorkandhumber-leedswest@nhs.net

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

Copy to: *Ms Anne Gowing, Leeds Teaching Hospitals Trust*
Professor Eve Roman, University of York

NRES Committee Yorkshire & The Humber - Leeds West

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

Committee Members:

<i>Name</i>	<i>Profession</i>	<i>Present</i>	<i>Notes</i>
Dr Vera Neumann (Chair)	Consultant in Rehabilitation Medicine	Yes	
Mr Vishal Sharma	Research Fellow/PhD Student	Yes	

Also in attendance:

<i>Name</i>	<i>Position (or reason for attending)</i>
Miss Kirstie Penman	REC Assistant