NHS
Health Research Authority
National Research Ethics Service

NRES Committee London - Fulham
Barlow House
3rd Floor, 4 Minshull Street
Manchester
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21 May 2015

Mrs Emma Lawrie
Trial Coordinator - Haematology Trials Group
UKALL14 Trial
Cancer Research UK & UCL Cancer Trials Centre
90 Tottenham Court Road
London
W1T 4TJ

Dear Mrs Lawrie

Study title:	**UKALL14 - A randomized trial for adults with newly diagnosed acute lymphoblastic leukemia**
REC reference:	**09/H0711/90**
Protocol number:	**UCL/08/0167**
EudraCT number:	**2009-012717-22**
Amendment number:	
Amendment date:	**29 April 2015**
IRAS project ID:	**23389**

The Substantial Amendment made clarifications to the Participant Information Sheet and Informed Consent Form, necessary to ensure the nature of the data being shared with central laboratories and seek the explicit consent for this information to be shared.

The above amendment was reviewed on 20 May 2015 by the Sub-Committee in correspondence.

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 on headed paper		29 April 2015
Notice of Substantial Amendment (CTIMP)		29 April 2015
Other [Summary of Changes - Participant information sheet]	v5.1 to v5.2	29 April 2015
Other [Summary of Changes - Informed Consent Form from]	v1.1 to v1.2	29 April 2015

Participant consent form [UKALL14 Informed Consent Form]	1.2- Tracked	29 April 2015
Participant consent form [UKALL14 Informed Consent Form]	1.2- Clean	29 April 2015
Participant information sheet (PIS) [UKALL14 Participant information sheet]	5.2- Tracked	29 April 2015
Participant information sheet (PIS) [UKALL14 Participant information sheet]	5.2- Clean	29 April 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

This Committee is recognised by the United Kingdom Ethics Committee Authority under the Medicines for Human Use (Clinical Trials) Regulations 2004, and is authorised to carry out the ethical review of clinical trials of investigational medicinal products.

The Committee is fully compliant with the Regulations as they relate to ethics committees and the conditions and principles of good clinical practice.

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/

09/H0711/90:	**Please quote this number on all correspondence**

Yours sincerely

pp K. Southern

On behalf of Dr Charles Mackworth-Young
Chair

E-mail: nrescommittee.london-fulham@nhs.net

Copy to: *Anna Jones, Royal Free London NHS Foundation Trust*
Adele Fielding, Royal Free Hospital
Miss Jo Gambell, CR UK & UCL Cancer Trials Centre

NRES Committee London - Fulham

Attendance at Sub-Committee of the REC meeting on 20 May 2015

Committee Members:

Name	*Profession*	*Present*
The Rev'd Nigel Griffin	Parish Priest	Yes
Dr Charles Mackworth-Young	Physician (Chairman)	Yes

Also in attendance:

Name	*Position (or reason for attending)*
Miss Anna Bannister	REC Manager
Miss Katie Southeard	REC Assistant