



Health Research Authority
National Research Ethics Service

NRES Committee London - Fulham

Barlow House
3rd Floor, 4 Minshull Street
Manchester
M1 3DZ

23 February 2015

Adele Fielding
Royal Free Hospital
1st floor, Rowland Hill Street
London
NW3 2PF

Dear Adele Fielding

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: 27 January 2015
IRAS project ID: 23389

The Substantial Amendment updated the Protocol from v6.0 to v6.1.

The above amendment was reviewed on 23 February 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:

<i>Document</i>	<i>Version</i>	<i>Date</i>
Covering letter on headed paper		04 February 2015
Notice of Substantial Amendment (CTIMP)		27 January 2015
Research protocol or project proposal [UKALL14 Protocol]	6.1- Tracked	27 January 2015
Research protocol or project proposal [UKALL14 Protocol]	6.1- Clean	27 January 2015
Summary, synopsis or diagram (flowchart) of protocol in non technical language [UKALL14 Protocol Amendment v6.1 – Changes from v6]		

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
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Yours sincerely

PP 

**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
Miss Jo Gambell*

NRES Committee London - Fulham

Attendance at Sub-Committee of the REC meeting on 23 February 2015

Committee Members:

<i>Name</i>	<i>Profession</i>	<i>Present</i>	<i>Notes</i>
Dr Charles Mackworth-Young	Physician (Chairman)	Yes	
Mrs Katie Wilkinson	Clinical Trials Centre Manager	Yes	

Also in attendance:

<i>Name</i>	<i>Position (or reason for attending)</i>
Miss Anna Bannister	REC Manager
Miss Katie Southeard	REC Assistant