



Health Research Authority

National Research Ethics Service

NRES Committee London - Fulham

HRA NRES Centre Manchester
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02 April 2014

Mr Simon Purnell
Haematology Trials Group
CR UK & UCL Cancer Trials Centre
90 Tottenham Court Road, London
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Dear Mr Purnell

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: Substantial Amendment 13.03.14
Amendment date: 13 March 2014
IRAS project ID: 23389

- Amendment proposed changes to the Information Sheet and also change of PI at Pool Hospital

The above amendment was reviewed 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
Participant Information Sheet: UKALL14 - Tracked Changes	5.0	13 March 2014
European Commission Notification of Substantial Amendment Form	Substantial Amendment 13.03.14	13 March 2014
Participant Information Sheet: UKALL14 - Clean	5.0	13 March 2014

Patient Information Version History		
Summary of changes - from version 4.1		13 March 2014
Covering Letter		13 March 2014
Investigator CV	Dr Darshayani Furby	04 October 2013

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



Signed on behalf of:
Dr Charles Mackworth-Young
Chairman

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

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

Copy to: Anna Jones, Royal Free London NHS Foundation Trust
Adele Fielding, Royal Free Hospital

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Attendance at Sub-Committee of the REC meeting on 01 April 2014

<i>Name</i>	<i>Profession</i>	<i>Capacity</i>
Dr Charles Mackworth-Young	Physician (Chairman)	Expert
Dr Frank Miskelly	Physician (Vice-Chairman)	Expert

Also in attendance:

<i>Name</i>	<i>Position (or reason for attending)</i>
Miss Diane Catterall	REC Assistant