



Health Research Authority

London - Fulham Research Ethics Committee

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

30 September 2015

Mrs Emma Lawrie
Trial Coordinator Haematology Trials Group
CR 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: Substantial Amendment
Amendment date: 11 September 2015
IRAS project ID: 23389

- Protocol
 - Optional additional sample for constitutional DNA studies.
 - Clarifications regarding transplant inclusion criteria and transplant conditioning regimens
 - Clarifications regarding scheduling of Nelarabine and contraindications to Nelarabine administration
 - Clarification of SAE reporting timeframes; addition of an adverse event of special interest (venous thromboembolisms)
 - Change of contact details for central Minimal Residual Disease Laboratory
 - Various administrative changes and corrections
- PIS
 - Updated information regarding the side effects of nelarabine, and their potential severity
 - Additional information about chimerism and MRD monitoring following reduced intensity transplant
 - Additional detail about consolidation and maintenance
- Addition of new information sheets and consent for consent to DNA samples from non-leukaemic patients

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:

<i>Document</i>	<i>Version</i>	<i>Date</i>
Covering letter on headed paper		11 September 2015
Notice of Substantial Amendment (CTIMP)		11 September 2015
Other [Protocol Summary of Changes]		09 September 2015
Other [PIS Summary of Changes]		09 September 2015
Participant consent form [Buccal Swab]	1.0	09 September 2015
Participant consent form [Bone Marrow]	1.0	09 September 2015
Participant information sheet (PIS) [Clean & Tracked]	5.3	09 September 2015
Participant information sheet (PIS) [Additional Genetic Testing Buccal Swab]	1.0	09 September 2015
Participant information sheet (PIS) [Additional Genetic Testing Bone Marrow]	1.0	09 September 2015
Research protocol or project proposal [Clean & Tracked]	7.0	09 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

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*

London - Fulham Research Ethics Committee

Attendance at Sub-Committee of the REC meeting on 16 September 2015

Committee Members:

<i>Name</i>	<i>Profession</i>	<i>Present</i>	<i>Notes</i>
Dr Shaun Griffin	Executive Director of External Affairs	Yes	
Dr Charles Mackworth-Young	Physician (Chairman)	Yes	

Also in attendance:

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