Health Research Authority

National Research Ethics Service

**NRES Committee London - Fulham**
HRA NRES Centre Manchester
Barlow House
3rd Floor, 4 Minshull Street
Manchester
M1 3DZ

Telephone: 0161 625 7816
Facsimile: 0161 625 7299

09 July 2014

Mr Simon Purnell
Haematology Trials Group
Cancer Research UK & UCL Cancer Trials Centre
90 Tottenham Court Road
W1T 4TJ

Dear Mr Purnell

| | |
|---|---|
| **Study title:** | **UKALL14 - A randomized trial for adults with newly diagnosed acute lymphoblastic leukaemia** |
| **REC reference:** | **09/H0711/90** |
| **Protocol number:** | **UCL/08/0167** |
| **EudraCT number:** | **2009-012717-22** |
| **Amendment number:** | **Substantial Amendment 20.6.2014 (Protocol v6.0, PIS v5.1)** |
| **Amendment date:** | **20 June 2014** |
| **IRAS project ID:** | **23389** |

- The amendment consists of an updated Protocol.
- The Participant Information Sheet is also updated in line with new reference safety information.

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.

The Committee questioned the acronym HCsAg as detailed in the exclusion criteria, as this was not recognised, you provided clarification regarding this.

**Approved documents**

The documents reviewed and approved at the meeting were:

| *Document* | *Version* | *Date* |
|---|---|---|
| Covering letter on headed paper | | 20 June 2014 |

| | | |
|---|---|---|
| Notice of Substantial Amendment (CTIMP) | Substantial Amendment 20.6.2014 (Protocol v6.0, PIS v5.1) | 20 June 2014 |
| Other [Protocol Summary of Changes] | 6.0 | |
| Other [Patient Information Version History] | | |
| Participant information sheet (PIS) [Tracked Changes] | 5.1 | 16 June 2014 |
| Participant information sheet (PIS) [Clean] | 5.1 | 16 June 2014 |
| Research protocol or project proposal [Tracked update] | 6.0 | 20 June 2014 |

**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

**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
Miss Jo Gambell

**NRES Committee London - Fulham**

**Attendance at Sub-Committee of the REC meeting on 08 July 2014**

## Committee Members:

| *Name* | *Profession* | *Present* | *Notes* |
|---|---|---|---|
| Dr Akil Jackson | Research Fellow | Yes | |
| Dr Charles Mackworth-Young | Physician (Chairman) | Yes | |

## Also in attendance:

| *Name* | *Position (or reason for attending)* |
|---|---|
| Miss Diane Catterall | REC Assistant |