



# Health Research Authority

## London - Fulham Research Ethics Committee

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Tel: 0207 104 8021

09 March 2017

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

Dear Dr 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:** Substantial Amendment (Protocol v9) REC  
**Amendment date:** 22 February 2017  
**IRAS project ID:** 23389

- Target Recruitment Extended from 720 participants to 811.
- Change of Study end date to 31/12/2023
- Clarification has been added about the arrangements for central review of chimerism in patients who have reduced intensity allogeneic transplants.
- Change of PI at Aintree University Hospital from Dr Walla Sadik to Dr Jeffery Smith.

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 [Cover Letter ]              |                | 22 February 2017 |
| Notice of Substantial Amendment (CTIMP) [Amendment Form]     |                | 22 February 2017 |
| Other [PIS Summary of Changes ]                              | 7              | 17 February 2017 |
| Other [Dr Smith CV ]   |                | 13 October 2015  |
| Participant information sheet (PIS) [PIS - Clean ]           | 7              | 17 February 2017 |
| Participant information sheet (PIS) [PIS - Tracked Changes ] | 7              | 17 February 2017 |

|   |   |                  |
|---|---|------------------|
| Research protocol or project proposal [Protocol - Clean ]           | 9 | 17 February 2017 |
| Research protocol or project proposal [Protocol - Tracked Changes ] | 9 | 17 February 2017 |
| Research protocol or project proposal [Protocol Summary of Changes] | 9 | 17 February 2017 |

### **Membership of the Committee**

The members of the Committee who took part in the review are listed on the attached sheet.

### **Working with NHS Care Organisations**

Sponsors should ensure that they notify the R&D office for the relevant NHS care organisation of this amendment in line with the terms detailed in the categorisation email issued by the lead nation for the study.

### **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 Research Ethics Committee members' training days – see details at <http://www.hra.nhs.uk/hra-training/>

|                     |   |
|---------------------|---|
| <b>09/H0711/90:</b> | <b>Please quote this number on all correspondence</b> |
|---------------------|---|

Yours sincerely



**The Rev'd Nigel Griffin (Chair)**  
**Chair**

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  
Miss Jo Gambell*

## London - Fulham Research Ethics Committee

### Attendance at Sub-Committee of the REC meeting on 01 March 2017

#### Committee Members:

| <i>Name</i>                     | <i>Profession</i>                     | <i>Present</i> | <i>Notes</i> |
|---------------------------------|---------------------------------------|----------------|--------------|
| Dr Anthony Farrant              | Lecturer in Healthcare Law and Ethics | Yes            |              |
| The Rev'd Nigel Griffin (Chair) | Parish Priest                         | Yes            |              |

#### Also in attendance:

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