

30 October 2017

Amy Douglas  
Trial Coordinator – Haematology Trials Group  
Cancer Research UK & UCL Cancer Trials Centre  
90 Tottenham Court Road  
London, W1T 4TJ

Dear Amy Douglas

**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:** Protocol Amendment 11  
**Amendment date:** 18 October 2017  
**IRAS project ID:** 23389

- Addition of a 'registration only' sub-study to the UKALL14 trial.
- Send samples to local chimerism laboratory rather than the central chimerism laboratory.
- Instructions have been added about how to register patients by email while maintaining compliance with current UCL CTC data protection policies.
- Change of PI Royal Devon and Exeter Hospital from Dr Jackie Ruell to Dr David Veale

The above amendment was reviewed at the meeting of the Sub-Committee held on 18 October 2017.

### Ethical opinion

The Committee had no ethical issues.

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		18 October 2017
Notice of Substantial Amendment (CTIMP)	Protocol Amendment 11	18 October 2017
Participant information sheet (PIS) ['Registration Only' sub-study -	2.0	11 September 2017

Clean]		
Participant information sheet (PIS) ['Registration Only' sub-study - Tracked]	2.0	11 September 2017
Participant information sheet (PIS) [Patient Information Sheet - Clean]	9.0	11 September 2017
Participant information sheet (PIS) [Patient Information Sheet - Tracked]	9.0	11 September 2017
Research protocol or project proposal [Clean]	11	11 September 2017
Research protocol or project proposal [Tracked]	11	11 September 2017
Research protocol or project proposal [Protocol Summary of Changes]	11	11 September 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>
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Yours sincerely



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

E-mail: [nrescommittee.london-fulham@nhs.net](mailto: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 18 October 2017**

**Committee Members:**

<i>Name</i>	<i>Profession</i>	<i>Present</i>	<i>Notes</i>
The Rev'd Nigel Griffin (Chair)	Parish Priest	Yes	
Miss Lesley Honeyfield	Principal Research Radiographer for the Imaging Department	Yes	

**Also in attendance:**

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