



**National Research Ethics Service**  
**West London REC 2**

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Miss Jo Gambell  
Haematology Trials Group  
CR UK & UCL Cancer Trials Centre  
90 Tottenham Court Road, London  
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Dear Miss Jo Gambell

07 June 2010

**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:** 1(Substantial)  
**Amendment date:** 20 May 2010

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        |
|--|----------------|-------------|
| Protocol Version History                                       |                |             |
| Protocol   | 2.0            | 17 May 2010 |
| European Commission Notification of Substantial Amendment Form | 1(Substantial) | 20 May 2010 |
| Covering Letter  |                | 20 May 2010 |
| Patient information version history                            |                |             |
| Participant Consent Form: Pregnant Partner                     | 1.0            | 17 May 2010 |
| Participant Information Sheet: Pregnant Partner                | 1.0            | 17 May 2010 |
| Participant Information Sheet                                  | 2.1            | 17 May 2010 |

**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 (July 2001) and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

**09/H0711/90:**

**Please quote this number on all correspondence**

Yours sincerely



**Ms Lucia Gavalova**  
**Committee Co-ordinator**

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

*Copy to: Dr Adele Fielding, University College London  
R&D office for NHS care organisation at lead site*

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**Attendance at Sub-Committee of the REC meeting on 01 June 2010**

| <i>Name</i>                | <i>Profession</i>    | <i>Capacity</i> |
|----------------------------|----------------------|-----------------|
| Dr Charles Mackworth-Young | Consultant Physician | Expert          |
| Dr Ruth Williamson         | Radiologist          | Expert          |