



# 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

Tel: 0161 625 7821  
Fax: 0161 625 7299

17 May 2013

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

Dear Mr Purnell,

**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:** Email detailing information  
**Amendment date:** 15 May 2013  
**IRAS project ID:** 23389

- New safety information alert for Rituximab specifically in relation to severe skin reactions provided. Information Sheet has been updated to reflect this.

Thank you for your letter of 15 May 2013, notifying the Committee of the above amendment.

It is noted that you do not consider this to be a substantial amendment to the clinical trial authorisation, as defined in the Medicines for Human Use (Clinical Trials) Regulations 2004, and that ethical review by the Committee is therefore not required.

#### Documents received

The documents received were as follows:

Document	Version	Date
Letter from Roche Pharmaceuticals		01 April 2013
Participant Information Sheet: Clean	4.1	16 May 2013
Participant Information Sheet: Tracked	4.1	16 May 2013
Notification of a Minor Amendment	Email detailing information	15 May 2013

## 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.

**09/H0711/90:**

**Please quote this number on all correspondence**

Yours sincerely



**Miss Shehnaz Ishaq**  
**Committee Co-ordinator**

E-mail: [nrescommittee.london-fulham@nhs.net](mailto:nrescommittee.london-fulham@nhs.net)

Copy to:                    Dr Adele Kay Fielding, Royal Free Hampstead NHS Trust  
  
                                  Ms Anna Jones, Royal Free Hospital Foundation NHS Trust  
  
                                  Dr Laura Clifton-Hadley, Senior Trials Co-ordinator, Haematology  
                                  Trials Group