



# Health Research Authority

## National Research Ethics Service

### NRES Committee London - Fulham

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23 August 2012

Miss Jo Gambell  
Haematology Trials Group  
CR UK & UCL Cancer Trials Centre  
90 Tottenham Court Road, London  
W1T 4TJ

Dear Miss Gambell

<b>Study title:</b>	<b>UKALL14 - A randomized trial for adults with newly diagnosed acute lymphoblastic leukemia</b>
<b>REC reference:</b>	<b>09/H0711/90</b>
<b>Protocol number:</b>	<b>UCL/08/0167</b>
<b>EudraCT number:</b>	<b>2009-012717-22</b>
<b>Amendment number:</b>	<b>Substantial Amendment 03.08.2012 (Protocol v5.0, PIS v4.0, Pregnant Partner Information Sheets, change of MA holder for Oncaspar, updated Oncaspar SPC)</b>
<b>Amendment date:</b>	<b>03 August 2012</b>

Amendment to Protocol v5.0 as follows:

- Change to Patient Information Sheet and Change to Pregnancy Monitoring Information Sheets and Consent Forms.
- Marketing Authorisation Holder for Oncaspar has changed from Medac GmbH (Germany) to sigma-tau Rare Diseases SA (Madeira, Portugal).

The above amendment was reviewed on 19 August 2012 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	5.0 - Clean	20 July 2012
Covering Letter		03 August 2012
Protocol	5.0 - Tracked	20 July 2012
UKALL14 Protocol Version History		
Participant Information Sheet	4.0 - Tracked	01 August 2012
Participant Information Sheet	4.0 - Clean	01 August 2012
UKALL14 Patient Information Sheet - Summary of Changes		
Participant Consent Form: UKALL14 Pregnant Partner Consent Form (Superseded)	1.1	18 August 2010
Participant Information Sheet: UKALL14 Pregnant Partner Information Sheet (Superseded)	1.1	18 August 2010
Participant Consent Form: UKALL14 Pregnancy Monitoring Consent Form (Patient)	1.0	01 August 2012
Participant Consent Form: UKALL14 Pregnancy Monitoring Consent Form (Partner)	1.0	01 August 2012
Participant Information Sheet: UKALL14 Pregnancy Monitoring Information Sheet (Patient)	1.0	01 August 2012
Participant Information Sheet: UKALL14 Pregnancy Monitoring Information Sheet (Partner)	1.0	01 August 2012
UKALL14 Patient Information Version History		
UKALL14 Oncaspar (Pegylated Asparaginase) SPC June 2012		01 June 2012
European Commission Notification of Substantial Amendment Form	Substantial Amendment 03.08.2012 (Protocol v5.0, PIS v4.0, Pregnant Partner Information Sheets, change of MA holder for Oncaspar, updated Oncaspar SPC)	03 August 2012
UKALL14 Summary of Changes from Protocol v4.0 to v5.0		

## 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.

**09/H0711/90:**

**Please quote this number on all correspondence**

Yours sincerely



**Signed on behalf of:  
Dr Charles Mackworth-Young  
Chair**

E-mail: shehnaz.ishaq@northwest.nhs.uk

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

Copy to: Mrs Wendy Fisher, R & D Department, Royal Free Hospital  
Dr Adele Kay Fielding, Royal Free Hampstead NHS Trust  
Mr Nick McNally, University College London

**NRES Committee London - Fulham**

**Attendance at Sub-Committee of the REC meeting on 19 August 2012**

<i>Name</i>	<i>Profession</i>	<i>Capacity</i>
Dr Charles Mackworth-Young - Chairman	Consultant Physician	Expert
Dr Shirlony Morgan	Psychiatrist	Expert