London - Fulham Research Ethics Committee

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06 June 2016

Jessica Smith
Trial Co-ordinator (UKALL14)
Haematology Trials Group
CR-UK & UCL Cancer Trials Centre
90 Tottenham Court Road
London W1T 4TJ

Dear Jessica Smith

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**
Amendment date:	**18 May 2016**
IRAS project ID:	**23389**

The main changes relate to the closure of the palifermin randomisation.

Other significant changes to the protocol are:
- Changes resulting from a change in supplier for pegylated asparaginase due to a drug company acquisition.
- Changes to the pregnancy reporting period for the trial, to bring it into line with the pregnancy risk period for the IMPs.
- Removal of references to international arrangements as the planned collaboration with researchers in New Zealand will now not be going ahead.

PIS revised to include:
- Amended throughout to reflect the closure of palifermin randomisation.
- A brief comment has been added regarding some recently presented evidence from the GRAALL research group

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*
Covering letter on headed paper		18 May 2016
Notice of Substantial Amendment (CTIMP)		18 May 2016
Other [Protocol - Summary Of Changes]		
Other [PIS - Summary of Changes]		
Participant information sheet (PIS) [Clean & Tracked]	V6.0	12 May 2016
Research protocol or project proposal [Clean & Tracked]	V8.0	12 May 2016

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.

We are pleased to welcome researchers and R & D staff at our NRES committee members' training days – see details at http://www.hra.nhs.uk/hra-training/

09/H0711/90:	**Please quote this number on all correspondence**

Yours sincerely

The Rev'd Nigel Griffin
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*
Adele Fielding, Royal Free Hospital

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Attendance at Sub-Committee of the REC meeting on 25 May 2016

Committee Members:

Name	*Profession*	*Present*	*Notes*
The Rev'd Nigel Griffin	Parish Priest	Yes	
Ms Monsey McLeod	Pharmacist	Yes	

Also in attendance:

Name	*Position (or reason for attending)*
Miss Anna Bannister	REC Manager