London - Fulham Research Ethics Committee

Barlow House
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Tel: 0207 104 8021

14 August 2018

Adele Fielding
Royal Free Hospital
1st floor, Rowland Hill Street
London
NW3 2PF

Dear Adele Fielding

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 (Protocol v12) REC**
Amendment date:	**27 July 2018**
IRAS project ID:	**23389**

This amendment consists of a number of changes, including updates to the protocol regarding the 'registration only' sub-study, clarification regarding Oncaspar in the participant information sheet and further updates in connection with GDPR.

The above amendment was reviewed by the Sub-Committee in correspondence.

Ethical opinion

The Sub-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:

Document	*Version*	*Date*
Covering letter on headed paper		27 July 2018
Notice of Substantial Amendment (CTIMP)	Substantial Amendment (Protocol v12) REC	27 July 2018
Other [Transparency Statement]	1.0	11 June 2018
Other [Summary of Changes]	12.0	26 June 2018

Participant information sheet (PIS) [Tracked]	10.0	28 June 2018
Participant information sheet (PIS) [Clean]	10.0	28 June 2018
Participant information sheet (PIS) [Registration Only Tracked]	3.0	28 June 2018
Participant information sheet (PIS) [Registration Only Clean]	3.0	28 June 2018
Research protocol or project proposal [Clean]	12.0	26 June 2018
Research protocol or project proposal [Tracked]	12.0	26 June 2018

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/

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

Yours sincerely

Dr Shaun Griffin
Vice 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*
Miss Jo Gambell

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Attendance at Sub-Committee of the REC meeting on 01 August 2018

Committee Members:

Name	*Profession*	*Present*	*Notes*
Dr Shaun Griffin	Communications Manager	Yes	
Ms Lesley Honeyfield	Research Radiographer	Yes	

Also in attendance:

Name	*Position (or reason for attending)*
Mr Ewan Waters	REC Assistant