

NRES Committee London - Fulham

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16 May 2012

Dr Adele Fielding
Royal Free Hampstead NHS Trust
Pond Street
London
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Dear Dr 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: Urgent Safety Measure 24.04.12
Amendment date: 24 April 2012

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	4.0 - clean	24 April 2012
European Commission Notification of Substantial Amendment Form	Urgent Safety Measure 24.04.12	24 April 2012
Protocol	4.0 - tracked	24 April 2012

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 – Royal Free Hospital

Miss Jo Gambell – Cancer Research UK and UCL Cancer Trials Centre

Nick McNally – University College London

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Attendance at Sub-Committee of the REC meeting on 16 May 2012

<i>Name</i>	<i>Profession</i>	<i>Capacity</i>
Dr Charles Mackworth-Young	Consultant Physician	None
Dr Ruth Williamson	Radiologist	Expert