National Research Ethics Service
Charing Cross Research Ethics Committee
Room 4W/12, 4th Floor
Charing Cross Hospital
Fulham Palace Road
London, W6 8RF
Telephone: 020 8846 7283
Facsimile: 020 8846 7280

COPY

RECEIVED
08 FEB 2010

Dr Adele Fielding
Senior Lecturer and Honorary Consultant in Haematology
University College London
Royal Free Campus, Rowland Hill Street
London
NW3 2PF

Dear Dr Fielding

13 January 2010 *(corrected 14 January 2010)*

Study Title:	**UKALL14 - A randomized trial for adults with newly diagnosed acute lymphoblastic leukemia**
REC reference number:	**09/H0711/90**
Protocol number:	**1.0**
EudraCT number:	**2009-012717-22**

Thank you for your letter of 24 December 2009, responding to the Committee's request for further information on the above research and submitting revised documentation.

The further information has been considered on behalf of the Committee by the Chair.

Confirmation of ethical opinion
On behalf of the Committee, I am pleased to confirm a favourable ethical opinion for the above research on the basis described in the application form, protocol and supporting documentation as revised, subject to the conditions specified below.

Ethical review of research sites
The favourable opinion applies to all NHS sites taking part in the study, subject to management permission being obtained from the NHS/HSC R&D office prior to the start of the study (see "Conditions of the favourable opinion" below).

The Committee has not yet been notified of the outcome of any site-specific assessment (SSA) for the non-NHS research site(s) taking part in this study. The favourable opinion does not therefore apply to any non-NHS site at present. I will write to you again as soon as one Research Ethics Committee has notified the outcome of a SSA. In the meantime no study procedures should be initiated at non-NHS sites.

Conditions of the favourable opinion
The favourable opinion is subject to the following conditions being met prior to the start of the study.

Management permission or approval must be obtained from each host organisation prior to the start of the study at the site concerned.

For NHS research sites only, management permission for research ("R&D approval") should be obtained from the relevant care organisation(s) in accordance with NHS research governance arrangements. Guidance on applying for NHS permission for research is available in the Integrated Research Application System or at http://www.rdforum.nhs.uk.
Where the only involvement of the NHS organisation is as a Participant Identification

Centre, management permission for research is not required but the R&D office should be notified of the study. Guidance should be sought from the R&D office where necessary.

Sponsors are not required to notify the Committee of approvals from host organisations.

Clinical trial authorisation must be obtained from the Medicines and Healthcare products Regulatory Agency (MHRA).

The sponsor is asked to provide the Committee with a copy of the notice from the MHRA, either confirming clinical trial authorisation or giving grounds for non-acceptance, as soon as this is available.

It is the responsibility of the sponsor to ensure that all the conditions are complied with before the start of the study or its initiation at a particular site (as applicable).

Approved documents
The final list of documents reviewed and approved by the Committee is as follows:

Document	*Version*	*Date*
Covering Letter		11 November 2009
REC application		16 November 2009
Investigator's Brochure (Epratuzumab)	4	30 August 2005
Investigator CV		16 October 2009
Evidence of insurance or indemnity		15 May 2009
Summary/Synopsis	1.0	11 November 2009
Sample Diary/Patient Card	1.0	11 November 2009
Questionnaire: General Health Questionnaire - Validated	GHQ-12	11 November 2009
Questionnaire: Oral Daily Mucositis Questionnaire - Validated	ODMQ	11 November 2009
GP/Consultant Information Sheets	1.0	11 November 2009
Letter from Sponsor		25 March 2009
Copy of Insurance Certificate		
Oncaspar - summary of product characteristics	Final Version	01 December 2008
Kepivance - product characteristics		17 July 2008
Atriance - product characteristics		12 December 2008
Mabthera - product characteristics		04 December 2008
Protocol	1.0	11 November 2009
Participant Consent Form	1.0	11 November 2009
Covering Letter		24 December 2009
Participant Information Sheet: Clean version	2.0	24 December 2009
Participant Information Sheet: Tracked Version	2.0	24 December 2009
Response to Request for Further Information		24 December 2009

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 (July 2001) and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

After ethical review
Now that you have completed the application process please visit the National Research Ethics Service website > After Review

You are invited to give your view of the service that you have received from the National Research Ethics Service and the application procedure. If you wish to make your views known please use the feedback form available on the website.

The attached document *"After ethical review – guidance for researchers"* gives detailed guidance on reporting requirements for studies with a favourable opinion, including:

- Notifying substantial amendments
- Adding new sites and investigators
- Progress and safety reports
- Notifying the end of the study

The NRES website also provides guidance on these topics, which is updated in the light of changes in reporting requirements or procedures.

We would also like to inform you that we consult regularly with stakeholders to improve our service. If you would like to join our Reference Group please email referencegroup@nres.npsa.nhs.uk.

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

Yours sincerely

Lucia Gavalova

pp
Dr Charles Mackworth-Young
Chair

Email: Lucia.Gavalova@imperial.nhs.uk

Enclosures: "After ethical review – guidance for researchers"

Copy to: *Miss Jo Gambell*
R&D office for NHS care organisation at lead site