faxed to DNL1 3/6/04.

Hull & East Riding Local Research
Ethics Committee
Room C24
College House
Willerby Hill Business Park
Willerby
HULL
HU10 6NS

18 May 2004

Professor D Cunningham
Consultant Oncologist
Royal Marsden Hospital
Downs Road
Sutton
Surrey
SM2 5PT

Dear Professor Cunningham,

Full title of study: R-CHOP 14 versus 21: A Phase III Multi-centre, randomised, clinical trial comparing Rituximab with CHOP given every 14 days and Rituximab with CHOP given every 21 days for the treatment of patients with newly diagnosed diffuse large B cell Non-Hodgkin's Lymphoma

REC reference number: 04/Q1104/27

Protocol number: 1.0

The Research Ethics Committee reviewed the above application at the meeting held on 17 May 2004. The committee wish to thank Dr Russell Patmore for attending the meeting in support of the above named application.

Ethical opinion

- Members agreed that patients should be given a separate consent form to enable them to agree to the storage of the fragment of Lymphoma Tissue for future use in research (as per GMC Guidelines). It should be made clear to the patient in the information sheet that the donation of this sample is voluntary

- It was suggested that in the paragraph entitled "What will happen to me during the study?" that the first paragraph should make it clear that the tests highlighted are done as a routine whether they are participating in the study or not

The members of the Committee present gave a favourable ethical opinion to the above research on the basis described in the application form, protocol and supporting documentation.

Conditions of approval

The favourable opinion is given provided that you comply with the conditions set out in the attached document. You are advised to study the conditions carefully.

Approved documents

The documents reviewed and approved at the meeting were:

Document Type: Application
Version: 1
Dated: 22/04/2004
Date Received: 04/05/2004

Document Type: Investigator CV
Version:
Dated: 04/05/2004
Date Received: 04/05/2004

Document Type: Protocol
Version: 1.0
Dated: 28/04/2004
Date Received: 04/05/2004

Document Type: GP/Consultant Information Sheets
Version: 1.0 Appendix 5 GP letter
Dated: 04/05/2004
Date Received: 04/05/2004

Document Type: Participant Information Sheet
Version: 1.0
Dated: 28/04/2004
Date Received: 04/05/2004

Document Type: Participant Consent Form
Version: 1.0
Dated: 28/04/2004
Date Received: 04/05/2004

Document Type: Other
Version: Letter from CRUK
Dated: 17/09/2003
Date Received: 04/05/2004

Document Type: Other
Version: Referees Comments
Dated: 01/10/2003
Date Received: 04/05/2004

Document Type: Other
Version: letter to Research Manager at CRUK
Dated: 02/10/2003
Date Received: 04/05/2004

Document Type: Other
Version: letter from CRUK
Dated: 13/10/2003
Date Received: 04/05/2004

Document Type: Other
Version: Trial Outline
Dated: 04/05/2004
Date Received: 04/05/2004

Management approval

If you are the Principal Investigator for the lead site: You should obtain final management approval from your host organisation before commencing this research.

The study should not commence at any other site until the local Principal Investigator has obtained final management approval from the relevant host organisation.

All researchers and research collaborators who will be participating in the research must obtain management approval from the relevant host organisation before commencing any research procedures. Where a substantive contract is not held with the host organisation, it may be necessary for an honorary contract to be issued before approval for the research can be given.

Membership of the Committee

The members of the Ethics Committee who were present at the meeting are listed on the attached sheet.

Statement of compliance *(from 1 May 2004)*

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 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.

REC reference number: 04/Q1104/27 **Please quote this number on all correspondence**

Yours sincerely

Mr Graeme Duthie
Chairman