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NHS
National Research Ethics Service

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22 April 2010

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

RECEIVED
26 APR 2010
ROYAL MARSDEN HOSPITAL - SUTTON
PROF. D. CUNNINGHAM

Dear Professor Cunningham

Study title:	**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 Lymphona**
REC reference:	**07/Q0501/49**
Protocol number:	**1.0**
EudraCT number:	**2004-002197-34**
Amendment number:	**11**
Amendment date:	**30 March 2010**

The above amendment was reviewed at the meeting of the Sub-Committee held on 21 April 2010.

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
Sub Study: Consent Form	4.0	

Sub Study: Information Sheet	4.0	
Sub Study: Protocol	5.0	
GP/Consultant Information Sheets	4.0	
Participant Consent Form	5.0	
Participant Information Sheet	5.0	
Protocol	6.0	
European Commission Notification of Substantial Amendment Form		30 March 2010
Details of new sites and PI's		

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

07/Q0501/49:	**Please quote this number on all correspondence**

Yours sincerely

Ms Rosemary Brown
Committee Co-ordinator

E-mail: rosemary.brown@royalfree.nhs.uk

Enclosures: *List of names and professions of members who took part in the review*

Copy to:

[R&D office for NHS care organisation at lead site]

North West London REC 2

Attendance at Sub-Committee of the REC meeting on 21 April 2010

Name	*Profession*	*Capacity*
Ms Rosemary Brown	Co-ordinator	None
Ms Marisa Lanzman	Clinical Trial Pharmacist	Expert
Dr Michael Pegg	Chairman	Expert
Sia Rafiee	Clinical Trial Pharmacist	Expert
Mrs Wendy Spicer	Pharmacist	Expert