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National Research Ethics Service

Royal Free Hospital & Medical School
Research Ethics Committee
Royal Free Hospital NHS Trust
Royal Free Hospital
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London
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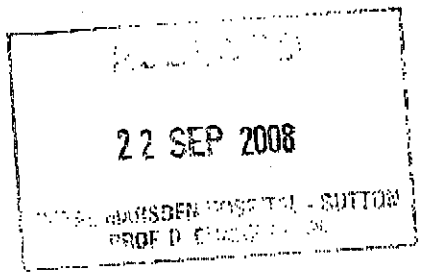

18 September 2008

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

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**
EudraCT number:	**2004-002197-34**
Amendment number:	**AM10**

The above amendment was reviewed at the meeting of the Sub-Committee of the REC held on 17 September 2008.

Ethical opinion

The members of the Committee present 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	5.0	07 July 2008
Participant Information Sheet: Sub-Study	3.0	18 July 2008
Participant Information Sheet	4.0	07 July 2008
Participant Consent Form	4.0	07 July 2008
Participant Consent Form: Sub-Study	3.0	18 July 2008
Tracked Changes		
Sub-Study Protocol	4.0	18 July 2008

GP/Consultant Information Sheets	3.0	07 July 2008
Covering Letter		26 August 2008
Annex 2 Notification of Amendment (CTIMPs)		

Membership of the Committee

The members of the Committee who were present at the meeting 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

Thomas McQuillan
Committee Co-ordinator
E-mail: Thomas.mcquillan@royalfree.nhs.uk

Enclosures List of names and professions of members who were present at the meeting and those who submitted written comments

Royal Free Hospital & Medical School Research Ethics Committee

Attendance at Sub-Committee of the REC meeting on 17 September 2008

Name	*Profession*	*Capacity*
Mr John Farrell	Head of Pharmaceutical Services	Expert
Ms Marisa Lanzman	Clinical Trial Pharmacist	None
Dr Michael Pegg	Chairman	Expert