



National Research Ethics Service

Royal Free Hospital & Medical School

Research Ethics Committee

Royal Free Hospital NHS Trust

Royal Free Hospital

South House, Block A

Pond Street

London

NW3 2QG

23 August 2007

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 Lymphoma

REC reference: 07/Q0501/49

Protocol number: 1.0

EudraCT number: 2004-002197-34

Amendment number: AM05

Amendment date:

The above amendment was reviewed at the meeting of the Sub-Committee of the REC held on 22 August 2007.

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	4.0	26 July 2007
Participant Information Sheet: Sub-Study	2.0	26 July 2007

Participant Information Sheet	3.0	26 July 2007
Participant Consent Form: Sub-Study	2.0	26 July 2007
Participant Consent Form	3.0	26 July 2007
PET Sub-Study Protocol	3.0	26 July 2007
Covering Letter		26 July 2007
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
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Enclosures List of names and professions of members who were present at the meeting and those who submitted written comments

Copy to: Clinical Trials Unit, MHRA

Royal Free Hospital & Medical School Research Ethics Committee**Attendance at Sub-Committee of the REC meeting on 22 August 2007**

<i>Name</i>	<i>Profession</i>	<i>Capacity</i>
Mr John Farrell	Head of Pharmaceutical Services	Expert
Ms Marisa Kaye	Clinical Trial Pharmacist	None
Dr Michael Pegg	Chairman	Expert