London - Hampstead Research Ethics Committee

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23 March 2016

Professor David Cunningham
Consultant Medical Oncologist
The Royal Marsden NHS Foundation Trust
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:	**Protocol v9.0**
Amendment date:	**15 March 2016**

- **Approval is sought to provide data to international collaborators.**

The above amendment was reviewed at the meeting of the Sub-Committee held on 23 March 2016 by the Sub-Committee in correspondence.

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.

There were no ethical issues raised.

Approved documents

The documents reviewed and approved at the meeting were:

Document	*Version*	*Date*
Covering letter on headed paper		15 March 2016
Notice of Substantial Amendment (CTIMP)	Protocol v9.0	15 March 2016

Research protocol or project proposal [Clean]	9.0	03 March 2016
Research protocol or project proposal [Tracked Changes]	9.0	03 March 2016

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 and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

We are pleased to welcome researchers and R & D staff at our NRES committee members' training days – see details at http://www.hra.nhs.uk/hra-training/

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

Yours sincerely

Signed on behalf of
Miss Stephanie Ellis
Chair

E-mail: nrescommittee.london-hampstead@nhs.net

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

London - Hampstead Research Ethics Committee

Attendance at Sub-Committee of the REC meeting on 23 March 2016

Committee Members:

Name	*Profession*	*Present*	*Notes*
Miss Stephanie Ellis	Former Civil Servant	Yes	Chaired meeting
Ms Ann Rosenthal	Literary Consultant (Retired)	Yes	

Also in attendance:

Name	*Position (or reason for attending)*
Miss Amber Ecclestone	REC Assistant