



Health Research Authority

NRES Committee London - Hampstead

Skipton House
Ground Floor, NRES/HRA
80 London Road
London
SE1 6LH

Tel: 020 797 22580

27 November 2012

Professor D Cunningham

Royal Marsden Hospital
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

EudraCT number: 2004-002197-34

Amendment number: Substantial Amendment- 29.10.12

Amendment date: 29 October 2012

The above amendment was reviewed by the Sub-Committee in correspondence.

Ethical opinion

No ethical issues.

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
Track Changed	8	19 October 2012
Protocol	8	19 October 2012
European Commission Notification of Substantial Amendment Form	Substantial Amendment- 29.10.12	29 October 2012

Covering Letter	Substantial Amendment- Clarification of the Methods of Pathology Review	29 October 2012
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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.

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

A handwritten signature in black ink, appearing to be 'SE', with the initials 'PP' written above it.

Miss Stephanie Ellis
Chair

E-mail: NRESCCommittee.London-Hampstead@nhs.net

NRES Committee London - Hampstead

Attendance at Sub-Committee held in correspondence

Written comments received from:

<i>Name</i>	<i>Position</i>
Miss Stephanie Ellis	Former Civil Servant
Mrs Wendy Spicer	Pharmacist