NHS
National Research Ethics Service

NRES Committee London - Hampstead
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27 April 2011

Jo Gambell
Senior Trial Coordinator
Cancer Research UK & UCL Cancer Trials Centre
90 Tottenham Court Road
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Dear Jo Gambell

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:	**Substantial Amendment 17.03.2011 (Main Protocol v7.0,PET sub study protocol v6.0)**
Amendment date:	**04 April 2011**

The above amendment was reviewed at the meeting of the Sub-Committee held on 20 April 2011.

Ethical opinion

The members of the sub-committee raised 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
Protocol	V7.0 - clean	17 March 2011
European Commission Notification of Substantial Amendment Form		04 April 2011
Covering Letter	Letter from Jo Gambell	04 April 2011
Protocol	V7.0 - tracked	17 March 2011
Protocol	V6.0 - clean (PET substudy Protocol)	17 March 2011

Protocol	V6.0 - tracked (PET substudy Protocol)	17 March 2011

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

Dr Michael Pegg
Chair

E-mail: junsakuma@nhs.net

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

Copy to:

Professor David Cunningham
Consultant Oncologist
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NRES Committee London - Hampstead

Attendance at Sub-Committee of the REC meeting on 20 April 2011

Name	*Profession*	*Capacity*
Dr Michael Pegg	Consultant Anaesthetist	Expert
Mr Sia Rafiee	Pharmacist - Clinical Trials	Expert

Also in attendance:

Name	*Position (or reason for attending)*
Mrs Alka Bhayani	Research Ethics Coordinator