



National Research Ethics Service
NRES Committee London - Hampstead

Northwick Park Hospital REC Centre
Level 7, Maternity Block
Northwick Park Hospital
Watford Road
Harrow
Middx HA1 3UJ

Tel: 020 8869 2915
Fax: 020 8869 5222

27 July 2011

Jo Gambell
Senior Trial Coordinator
Haematology Trials Group
Cancer Research UK & UCL Cancer Trials Centre
90 Tottenham Court Road
London W1T 4TJ

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 Lymphoma

REC reference: 07/Q0501/49

EudraCT number: 2004-002197-34

Amendment number: Revised GP letter

Amendment date: 15 July 2011

Thank you for your letter of 15 July 2011, notifying the Committee of the above amendment.

It is noted that you do not consider this to be a substantial amendment to the clinical trial authorisation, as defined in the Medicines for Human Use (Clinical Trials) Regulations 2004, and that ethical review by the Committee is therefore not required.

Documents received

The documents received were as follows:

Document	Version	Date
GP letter	4.2, clean copy	15 July 2011
GP letter	4.2, tracked changes	15 July 2011
Notification of a Minor Amendment	Letter from Jo Gambell	15 July 2011

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



Mrs Alka Bhayani
Committee Co-ordinator

E-mail: alkabhayani@nhs.net

Copy to:

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