NHS

Hull and East Riding Local Research Ethics Committee

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24 August 2005

Ms Cathy Burton
R CHOP Trial Management Group
Cancer Research UK & UCL Cancer Trials Office
Lymphoma Trials Office
222 Euston Road
London
NW1 2DA

Dear Ms Burton,

Study title: **A Phase III multicentre 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: **04/Q1104/27**
Protocol number: **version 1.0**
EudraCT number: **2004-002197-34**

Amendment number: **2.0**
Amendment date: **03/08/2005**

The above amendment was reviewed by the Chair and Vice-chair at the meeting of the Committee held on 15th August 2005.

Ethical opinion

The information relating to all 8 points of the amendment were reviewed and a favourable ethical opinion given for 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:

- Covering letter dated 3rd August 2005
- Annexe 2 Notification of Amendment form dated 04/08/2005
- Copy of Protocol version 1.0 dated 28/04/2004
- Copy of Protocol version 2.0 dated 03/08/2005

Research governance approval

All investigators and research collaborators in the NHS should notify the R&D Department for the relevant NHS care organisation of this amendment and check whether it affects research governance 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.

04/Q1104/27	**Please quote this number on all correspondence**

Yours sincerely

L Carrison

Miss Louise Carrison
Committee Co-ordinator

Copy to: Clinical Trials Unit, MHRA
Professor D Cunningham Chief Investigator