



Hull and East Riding Local Research Ethics Committee

Coniston House (Trust Headquarters)  
Willerby Hill Business Park  
Willerby  
HULL  
HU10 6ED

Tel: 01482 389246  
Fax: 01482 303908

30 August 2006

Mr Paul Smith  
Cancer Research UK &  
UCL Cancer Trials Centre  
Stephenson House  
158-160 North Gower Street  
London  
NW1 2ND

Dear Mr Smith,

**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:** 04/Q1104/27

**Protocol number:** 3.0

**EudraCT number:** 2004-002197-34

**Amendment number:** 2

**Amendment date:** 31 July 2006

The above amendment was reviewed at the meeting of the Committee held on 21 August 2006.

**Ethical opinion**

The members of the Committee present 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	3.0	13 July 2006
Sub protocol collection and storage of buccal DNA samples	v1	24 March 2006
Sub protocol	2	01 April 2006
DOH Letter re ETC Application		25 July 2006
Covering Letter		31 July 2006
Annex 2 Notification of Amendment (CTIMPs)		31 July 2006

## Membership of the Committee

The members of the Ethics Committee who were present at the meeting are listed on the attached sheet.

## 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



**Mrs Louise Hunn**  
**Committee Co-ordinator**

E-mail: [louise.hunn@humber.nhs.uk](mailto:louise.hunn@humber.nhs.uk)

*Copy to: Clinical Trials Unit, MHRA*  
*Professor David Cunningham*  
*Mr Paul Mouncey*

*Enclosures List of names and professions of members who were present at the meeting*  
*and those who submitted written comments*

## Hull & East Riding Local Research Ethics Committee

Attendance at Committee meeting on 21 August 2006

### Committee Members:

<i>Name</i>	<i>Profession</i>	<i>Present?</i>	<i>Notes</i>
Mr Graeme Duthie	Reader in Surgery	Yes	
Mr Michael Davidson	Retired	Yes	
Mrs Eleanor Dakkak	Principal Pharmacist	No	
Dr Ivana Markova	Senior Lecturer & Honorary Consultant in Psychiatry	No	
Coun. Kay West	JP	Yes	
Mrs Sally Floyd	Health Visitor	Yes	
Dr David Horton	Consultant Radiologist	Yes	
Mrs Joanna Wild	Social Work - Psychosocial Palliative Care	No	
Mrs Helen Williams	NCT Antenatal Teacher	No	
Dr Andrew Innes	General Practitioner	Yes	
Dr Lynn Cawkwell	Non-Clinical Senior Lecturer in Cancer Genetics	Yes	
Mr Chris Meegan	Committee Member (LAY)	No	
Mr Sydney Howey	Committee Member (LAY)	Yes	
Mr A Mohsen	Consultant Orthopaedic & Trauma Surgeon	Yes	
Dr Nigel Steel	Consultant Physician	Yes	
Mrs Sue C Clark		No	
Mrs Louise Hunn	Administrator	Yes	

### Also in attendance:

<i>Name</i>	<i>Position (or reason for attending)</i>