NHS
Health Research Authority
NRES Committee East of England - Hertfordshire

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08 June 2012

Humra Shah
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Dear Shah

Study title:	**A Phase II Single Arm Study of the use of CODOX-M/IVAC with Rituximab (R-CODOX-M/IVAC) in the treatment of patients with Diffuse Large B-Cell Lymphoma (DLBCL) (Age-Adjusted International Prognostic Index (IPI) High or High-Intermediate Risk)**
REC reference:	**05/Q0201/81**
Protocol number:	**05/134**
EudraCT number:	**2005-003479-19**
Amendment number:	**Amendment 9.2 (REC Amendment #25 (minor)**
Amendment date:	**31 May 2012**
Amendment detail:	**Changes to the patient information sheet**

Thank you for your letter of 31 May 2012, 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
Participant Information Sheet: without tracked changes	7.3	18 May 2012
Participant Information Sheet: with tracked changes	7.3	18 May 2012
Notification of a Minor Amendment		31 May 2012

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.

05/Q0201/81:	**Please quote this number on all correspondence**

Yours sincerely

Sarah Clark
Committee Co-ordinator

E-mail:

Copy to: *N/A. R&D contact not specified in database.*

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