Cancer Research UK & UCL Cancer Trials Centre
University College London
90 Tottenham Court Road
London W1T 4TJ
Tel: +44 (0)20 7679 9538
Fax: +44(0)20 7679 9861
E-mail: r-codox-mivac@ctc.ucl.ac.uk
Website: www.ctc.ucl.ac.uk

9th August 2010

Ms Anna Bradnam
Hertfordshire REC
REC Office
Victoria House
Capital Park
Fulbourn
Cambridge
CB21 5XB

Dear Ms Bradnam,

RE: 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) or Burkitt's Lymphoma (BL) of International Prognostic Index High or High – Intermediate Risk

REC reference number: 05/Q0201/81
EudraCT Number: 2005-003479-19
Sponsor's Protocol number: UCL/05/134
Amendment 8.0 – 09.08.2010

On behalf of the sponsor, I request for authorisation of a substantial amendment made to the protocol of the above named trial.

A list of amendments made to the main protocol, are as follows (page numbers are as on the tracked version):

- Change of protocol cover page and authorisation signature page
- Additional information to the site selection section (section 3.0 pg 23)
- Addition of a section on Informed consent (section 4.0, pg 25)
- Change in the patient selection section; baseline investigations and eligibility criteria. Maximum age of inclusion has been increased from 60 years as stated in the original application to 65 years of age. Echocardiogram or nuclear medicine scan (MUGA) has been made mandatory for patients aged from 61 to 65 years. (sections 5.1 and 5.3.1, pgs26,28)

- Addition of sections on pregnancy /birth control and long term infertility (sections 5.3.3 and 5.3.4, pg 30)

- Additional sections on trial monitoring and oversight, withdrawal of patients and trial closure (sections 14.0, 15.0 & 16.0, pgs. 81 - 85)
- Additional information to the ethical and regulatory approvals section (section 18.0, pg 87 - 89)

- Additional sections on sponsorship & indemnity, funding and publication policy (section 19.0, 20.0 and 21.0, pgs 90 - 93)

- Removal of the expected toxicities for each chemotherapy drug from the appendix, and the addition of expected adverse events for the treatment regimen. The expected adverse events for each drug will be based on the individual SmPCs (appendix 9, pg 110)

Information given in the Patient Information Sheet and Consent form has been updated.

For detailed changes made to the protocol, see the 'Extract from the amended protocol' appended to the notification form.

I will forward the authorisation page of the protocol with the Chief Investigator's and sponsor representative's signatures as soon as I have them.

Please do not hesitate to contact me should you have any further queries.

Yours sincerely,

Toyin Adedayo
Clinical Trials Coordinator

Cc: MHRA

End: Annex 2, notification of amendment 8.0, 09.08.2010
Protocol- Version 7.0, 22.07.2010 (tracked changes & untracked)
Patient Information Sheet - Version 7.0, 23.06.2010 (tracked changes & untracked)
Pregnant Partner Information Sheet & Consent Form - Version 1.0, 01.07.10
Consent Form - Version 7.0, 23.06.2010 (tracked changes & untracked)
GP letter - Version 6.0, 23.06.2010 (tracked changes and untracked)
List of Detailed changes to Documents – 09.08.2010