



Royal Free and University College Medical School
University College London

Randomisation Line/General Enquiries
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**CANCER RESEARCH UK &
UCL CANCER TRIALS CENTRE**
The Lymphoma Trials Office
90 Tottenham Court Road
London, W1T 4TJ

Centre Director: Professor J A Ledermann

Thursday 13th September 2007

Ms Sue Oliver
Ambulance Training Centre
Via Location Code Q7
Qe11 Hospital
Howlands
Welwyn Garden City
Herts
AL7 4HQ

Dear Ms. Oliver

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) of Age-Adjusted International Prognostic Index (IPI) High or High-Intermediate Risk

REC reference number: 05/Q0201/81
Amendment 4.0 – 01.08.2007

Please find enclosed, copies of the following:

Annex 2, notification of amendment 4.0 28.08.2007
Protocol 01.08.2007 Version 4.0 (tracked changes), incl Patient Information Sheet, Consent Form and GP letter Version 4.0 01.08.2007.
Protocol 01.08.2007 Version 4.0 (untracked changes)
Signed Part B NRES form has been completed and signed by a medical expert from Nottingham University as the initial application pre-dated this requirement

A list of amendments made to the main protocol, are as follows:

- International Prognostic Index has replaced the Age Adjusted IPI in Appendix 1 pg44 and reference made to this has changed throughout the protocol.
- The Declaration of Helsinki has been added, appendix 11 pg 63.
- Reference to Rasburicase has been removed pg 7,9 and 13.
- Information on who will be supplying what drugs has been added to pg 13.
- Rituximab is now to be given on day 11 as opposed to day 10 set out on page 15.



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- Pg 32, section on safety reporting has had additions made to it, providing more comprehensive information to sites as well as a flow diagram on assessing and notifying the Lymphoma Trials Office of events.
- Pg 42, a reference has been removed.
- Appendix 3, pg 47, addition of information on prophylaxis has been added.
- Patient Information Sheet, pg 51, reference to 'age adjusted' has been removed as well as reference to Rasburicase .
- Consent form part I and II, pg 57 and 58, reference to 'age adjusted' has been removed.
- GP letter, pg59, reference to 'age adjusted' has been removed.
- Pg 62, contact details have changed for Cathy Burton.

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

Yours sincerely,

Rachel Haley
Clinical Trial Coordinator

Incl: annex 2, protocol v4.0 (tracked and untracked) and a signed Part B NRES form.



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