(Form to be printed on hospital/institution headed paper)

Site Name: <<insert site name>>
Patient ID: <<insert patient ID>>

PREGNANCY MONITORING CONSENT FORM
(for trial patients)

Name of Trial: R-CODOX-M/IVAC Trial - 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 (IPI) High or High-Intermediate Risk

Name of Principal Investigator: <<insert name of Principal Investigator>>

Please initial box

1.	I confirm that I have read and understand the information sheet dated ……… (version ……) and that the reasons for collecting these data have been explained to me. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.	
2.	I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care or legal rights being affected.	
3.	I understand that relevant sections of any of my medical notes and data collected regarding my pregnancy may be looked at by appropriate individuals from the Cancer Research UK & UCL Cancer Trials Centre, University College London, other participating groups and their funding bodies, relevant regulatory bodies, or from the institution where it is relevant to my taking part in research. I give permission for these individuals to have access to my records.	
4.	I voluntarily agree to provide the requested information.	

Name of patient   Date   Signature

_____ _____ _____

modified for R-CODOX-M/IVAC Trial on v1.0 15.03.11

Name of person taking consent   Date   Signature
(designated responsible person)

_____   _____   _____

When completed: Take 2 copies. Original and 1 copy to be kept in medical notes and investigator site file, and a copy to be given to the patient.

Data Protection Act 1998: This research project is registered for data protection and the requirements of the Act apply in full. The information held will be used for medical research purposes only and will be stored and disposed of in a secure manner.

modified for R-CODOX-M/IVAC Trial on v1.0 15.03.11

Pregnancy Monitoring ICF Template (Patient) v1 31.01.11