PATIENT CONSENT FORMS - PART I & II

Patient Trial Number | | | |

(*To be printed on local headed paper)*

PATIENT CONSENT FORM - PART I
Version 6.0
Date: 13.05.2009

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) or Burkitt's Lymphoma (BL) of International Prognostic Index (IPI) High or High-Intermediate Risk (MREC reference 05/Q0201/81)

PATIENT CONSENT FORM PART I* (please read carefully)

Name of Researcher: _____

	Please Initial
I confirm that I have read and understand the information dated 13.05.2009 (version 6.0) for the above study and have had an opportunity to ask questions.	
I understand that my participation in this study is voluntary and that I am free to withdraw at any time without giving a reason, without my medical care or legal rights being affected.	
I understand that sections of my medical notes may be looked at by responsible individuals involved in this research or from regulatory authorities where it is relevant to my taking part in research. I give permission for these individuals to have access to my records.	
I understand that samples of tissue taken will be reviewed by a pathologist in another hospital and that additional tests for biological risk factors will be performed	
I agree to take part in the above study.	

OPTIONAL

I agree for my GP to be informed	
I agree for information to be obtained from the Office of National Statistics	

___ _____ _____

Name of Patient Date Signature

_____ _____ _____

Name of person taking consent (if different from researcher) Date Signature

* Three copies required: one each for the patient, researcher and hospital case notes

Name of Researcher	Date	Signature

Patient Trial Number | | | |

(*To be printed on local headed paper)*

PATIENT CONSENT FORM - PART II
Version 6.0
Date: 13.05.2009
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) or Burkitt's Lymphoma (BL) of International Prognostic Index (IPI) High or High-Intermediate Risk (MREC reference 05/Q0201/81)

PATIENT CONSENT FORM PART II* (please read carefully)

Name of Researcher: _____

VOLUNTARY DONATION OF TISSUE SAMPLE

	Please Initial
I understand a small, anonymised fragment of the lymphoma tissue will be stored for future studies. I understand that this will be linked to the trial data through the unique trial number and no other personal data will be held. I understand separate ethics approval will be sought before the use of this material for future studies.	

Name of Patient	Date	Signature
Name of person taking consent (if different from researcher)	Date	Signature
Name of Researcher	Date	Signature

Patient Trial Number | | | |

(*To be printed on local headed paper)*

* Three copies required: one each for the patient, researcher and hospital case notes

ADDITIONAL PATIENT CONSENT FORM* (Please read Carefully)

Date: 13.05.2009

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) or Burkitt's lymphoma (BL) of International Prognostic Index (IPI) High or High-Intermediate Risk (MREC reference 05/Q0201/81)

	Please initial
I have received a copy of the Patient Information Sheet (version 6.0 dated 13.05.2009)	
I confirm that I have read and understood the additional information provided about Rituximab.	

Patient's name:	
Patient's signature:	
Date:	

Person designated by the investigator to participate in the informed consent process:

Name:	
Signature:	
Date:	

Investigator's name:	
Title/Position:	
Investigator's Signature:	
Date:	

* Three copies required: one each for the patient, researcher and hospital case notes