(To be printed on hospital/institution headed paper)

PREGNANCY MONITORING INFORMATION SHEET
(for partners of trial patients)

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

The purpose of this information sheet is to explain why the Cancer Research UK & UCL Cancer Trials Centre (CTC) would like to follow the progress of your pregnancy. The following information will help you decide if you would like to provide us with information about your pregnancy.

Please ask us to explain any words or information that you do not understand.

What is the purpose of collecting this information?
Your partner's doctor will have explained to you that your partner has been participating in a research study, also called a clinical trial, to test a treatment for his diffuse large B cell non-Hodgkin's lymphoma or Burkitt's lymphoma involving Rituximab, cyclophosphamide, doxorubicin, vincristine, methotrexate, etoposide, ifosfamide, cytarabine and Neulasta. Your partner was asked to use birth control while he was enrolled in the trial because the information provided for the trial treatment states that a developing foetus may be harmed by it.

We are asking you to provide information to the CTC and the trial doctor because your partner has reported that you became pregnant while he was enrolled in this trial. Your partner's doctor will have explained to you the possible risks of the trial treatment to your unborn child. The CTC has asked the trial doctor to collect information from you about your pregnancy to help better understand the effects of exposure to the trial treatment during pregnancy.

What are the possible disadvantages and risks of taking part?
There are no medical risks to you associated with collecting information about your pregnancy.

What will I have to do?
We are asking you (as a pregnant partner) to provide information concerning your pregnancy (for example, anticipated due date, any medication you have been taking and details of any previous pregnancies). You will be followed to determine the outcome of your pregnancy and may also be followed for up to 6 - 8 weeks following delivery of your child to collect information on any ante- or post-natal problems. We would also like to know if your pregnancy does not continue to term.

Do I have to provide information?
Your participation in providing information is entirely voluntary. If you agree, we will ask you to sign a consent form to show that you have agreed to provide information on your pregnancy. You may decide not to allow information about your pregnancy to be

collected or you may decide to allow it and then change your mind. Refusal to provide information will not result in any change in treatment to which you, or your partner, are otherwise entitled. If you decide to withdraw consent after providing some information, the CTC will only keep your information collected up to that point.

What are the possible benefits of allowing my information to be collected?
There will be no direct benefit to you by allowing the trial doctor or the CTC to follow the progress of your pregnancy. However, you may help scientists better understand the effects of exposure to the trial treatment during pregnancy.

Will my information be kept confidential?
All information collected about you and your pregnancy will be kept strictly confidential.

Your partner was assigned a unique trial number by the CTC when he entered the trial. Researchers use this number to keep track of information. To protect your privacy, any information collected about you and your pregnancy, including your initials and date of birth, will not be linked to your name or your partner's name and will only be linked to the trial number that has been assigned to your partner. Your partner's trial doctor and the trial team at the hospital will keep the link between your partner's patient number and your name. Your child's name will not be collected.

If you consent to information about your pregnancy being collected, it may be inspected by the company(ies) who are providing the trial medication or the sponsor (University College London) of the trial (including representatives of the sponsor), as well as the CTC who is coordinating the trial. These inspections are solely for the purposes of the research and analysing the results. Your records may also be looked at by regulatory authorities or ethics committees to check that the information is being collected and analysed appropriately.

The organisations listed above will keep information about you confidential. Your name will not be used in any reports and all information is stored securely and handled in accordance with the principles of the Data Protection Act 1998. Where there is a possibility that your information may be sent outside the UK for regulatory or research purposes, the CTC will take reasonable steps to ensure the principles of the Data Protection Act are maintained.

Thank you
Thank you for considering whether to provide this information and taking the time to read this information sheet.

Useful contacts
If you have questions about the trial your partner is participating in, or if you wish to withdraw from providing any additional information concerning your pregnancy, please contact the trial doctor or a member of the trial team at the hospital.

Useful contacts:

Local Contacts:

Trial doctor ..... Tel: .....

Trial nurse ..... Tel: .....

(Other contact) ..... Tel: .....