PREGNANCY MONITORING INFORMATION SHEET
(for partners of study patients)

Study 15 – A multicentre, randomised trial comparing combination gemcitabine/carboplatin and hydroxychloroquine versus carboplatin/etoposide therapy alone in small cell lung cancer (SCLC)

IRAS No.: 198726

The purpose of this information sheet is to explain why the Cancer Research UK & UCL Cancer Trials Centre (UCL 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 lung cancer involving chemotherapy. Your partner was asked to use birth control while he was enrolled in the study because the information provided for the study treatment states that a developing foetus may be harmed by it.

We are asking you to provide information to the UCL CTC and the study doctor because your partner has reported that you became pregnant while he was enrolled in this study. Your partner’s doctor will have explained to you the possible risks of the study treatment to your unborn child. The UCL CTC has asked the study doctor to collect information from you about your pregnancy to help better understand the effects of exposure to the study 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 to allow information about your pregnancy to be collected or you may change your mind and decide not to allow it. 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 UCL 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 study doctor or the UCL CTC to follow the progress of your pregnancy. However, you may help scientists better understand the effects of exposure to the study 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 study number by the UCL CTC when he entered the study. 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 study number that has been assigned to your partner. Your partner’s study doctor and the study 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 looked at by staff from UCL CTC, the sponsor (or representatives of the sponsor), regulatory authorities and your NHS Trust/Health Board. This is to ensure that the information is being collected is correct 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 UCL 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 study your partner is participating in, or if you wish to withdraw from providing any additional information concerning your pregnancy, please contact the study doctor or a member of the study team at the hospital.

Local Contacts:
Study doctor .................................................... Tel: .....................................................
Study nurse .......................................................... Tel: .....................................................
(Other contact) .......................................................... Tel: .....................................................