(To be printed on hospital/institution headed paper with CR-UK included)

PREGNANCY MONITORING INFORMATION SHEET
(for partners of study patients)

ANIMATE

A phase II study of nivolumab monotherapy in patients with relapsed/refractory Hodgkin lymphoma fit for autologous stem cell transplant who fail to reach complete metabolic remission after first or second line salvage therapy

IRAS No.: 216147

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 Hodgkin Lymphoma involving nivolumab. As recommended by the manufacturer of nivolumab, your partner was asked to use birth control during treatment and for a minimum of 8 months after completing trial treatment. This is because the effects of nivolumab on pregnancy and the developing foetus are not yet known or are not fully understood at this time, but it is possible that nivolumab could harm an unborn baby.

We are asking you to provide information to UCL CTC and the study doctor because your partner has reported that you became pregnant while he was either on study treatment, or within 8 months of completion of his trial treatment. Your partner's doctor will have explained to you the possible risks of the study treatment to your unborn child. 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, 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 8 weeks following delivery of your child to collect information on any ante- or post-natal problems, whether the pregnancy continued to term and if so, how the baby was after birth. This information is

important because it helps us to better understand the effect of the trial treatment on pregnancy and the unborn baby.

Do I have to provide information?
No. Whether or not you allow us to collect information about your pregnancy 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. If you decide that you do not want to allow us to collect this information, or if you agree and then later change your mind, this will not affect the care you or your partner receive in any way. If you change your mind we will stop collecting any more information, however information that has already been sent to the organisers of the study will be kept by them.

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.

Anonymised information relating to your pregnancy will be shared with Bristol-Myers Squibb, who are providing nivolumab for use in the trial, so they can monitor the safety of their drug, however it will not be possible to identify you from the information they are provided.

If you consent to information about your pregnancy being collected, it may be looked at by staff from UCL CTC, Bristol-Myers Squibb Pharmaceuticals Ltd, the sponsor (University College London, 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 General Data Protection Regulation (EU 2016/679) and UK Data Protection Act 2018~~Data Protection Act 1998~~.

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.

Useful contacts:

Local Contacts:

Study doctor ..... Tel: .....

Study nurse ..... Tel: .....

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