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

PREGNANCY MONITORING INFORMATION SHEET
(for 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

~~<<Study short and full names>>~~

IRAS No.: 216147~~[insert IRAS number]~~

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?
You have been participating in a clinical study to test a treatment for your Hodgkin Lymphoma~~[state type of cancer]~~ involving ~~[list trial treatment(s)]~~nivolumab and you have reported that you are pregnant between the start of your treatment and ~~xx~~8 months after the end of your treatment.

Your doctor will have explained to you that ~~the effects of the study treatment on pregnancy and the developing foetus are not yet known or are not fully understood at this time.*/~~ the information provided for the study treatment states that a developing foetus may be harmed by it. ~~*(*delete as applicable)*~~ UCL CTC has asked us 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 to provide information concerning your pregnancy (for example, anticipated due date, details of any previous pregnancies, any medication you have been taking and any other factors that may affect the pregnancy). We will collect information about you to determine the outcome of your pregnancy. You may also be followed for up to 6 weeks ~~*(cross check with protocol)*~~ following delivery of your child (or later if there are ongoing issues) to collect information on any ante-natal or post-natal problems. We would also like to know if your pregnancy does not continue to term. This information is important because it helps us to better understand the effect of the study treatment on pregnancy and the unborn baby.

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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 about 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 your treatment or medical care to which you 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 us and 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.

How will my data be handled?
All information collected about you and your pregnancy will be kept confidential. Your name or your child's name will not be used in any reports and all information is stored securely.

If you agree, we will provide information to UCL CTC (your age, anticipated due date, any medication you have been taking, details of any previous pregnancies and outcome of this pregnancy) and this will be linked to the unique study number you were assigned when you entered the study. This is called 'pseudonymised information', and UCL CTC cannot directly identify you from this. Your child's name will not be provided to UCL CTC.

If you consent to information about your pregnancy being collected, your medical records may also be looked at by appropriate individuals from UCL CTC, the sponsor (or representatives of the sponsor), regulatory authorities and your NHS Trust/Health Board ~~*(amend as appropriate, ensure this has been cross checked against the consent form for consistency)*~~. This is to ensure that the information collected is correct and analysed appropriately.

Pseudonymised information relating to your pregnancy will be shared by UCL CTC with Bristol-Myers Squibb Pharmaceuticals Ltd~~[insert name of drug company]~~, who are providing ~~[drug name]~~nivolumab for use in the study so that they can monitor the safety of their drug.

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 relevant data protection legislation are followed. Your name will not be used in any reports and all information is stored securely.

For further information relating to the collection and processing of your data for this study, please refer to the main Patient Information Sheet that you were given at the start of the study.

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

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Useful contacts

If you have any questions about the study you are participating in, or if you wish to withdraw from providing any additional information concerning your pregnancy, please contact your 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: .....

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