

(Form to be on hospital/institution headed paper with CR-UK included)

Site Name: << insert site name or site number >>

Patient Study ID: << insert patient study number >>

CONSENT FORM

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

Name of Principal Investigator: << insert name of Principal investigator >>

IRAS No.: 216147

Please initial box

1.	I confirm that I have read and understand the information sheet dated (version) for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.	<input type="checkbox"/>
2.	I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care or legal rights being affected.	<input type="checkbox"/>
3.	I understand that relevant sections of my medical notes and data collected during the study, may be looked at by individuals from the Cancer Research UK and UCL Cancer Trials Centre, Bristol-Myers Squibb Pharmaceuticals Ltd (the company funding the trial and providing study medication), the study sponsor, University College London and its representatives, regulatory authorities, or from the NHS Trust/Health Board where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records.	<input type="checkbox"/>
4.	I agree to my GP being informed of my participation in this study.	<input type="checkbox"/>
5.	I understand that up to four of my PET-CT scan images will be sent securely to St Thomas' Hospital, London for an expert to review. I give permission for my initials and trial number to be sent and stored in a secure location with the PET scan images. I understand that my scans may be used in research aimed at improving services and refining techniques for PET scan review.	<input type="checkbox"/>

6.	<p>I agree to gift up to six blood samples (taken before nivolumab, prior to cycles 2, 4, 6 and 8, and at the end of treatment) for use in research related to this study.</p> <p>I understand that gifting my samples for use in the trial is voluntary and that I am free to withdraw my approval for their use at any time without giving a reason and without my medical treatment or legal rights being affected.</p> <p>I understand that these samples will be marked with my initials, date of birth and trial number, and give permission for these identifiers to be shared with the Central Laboratories (Weatherall Institute of Molecular Medicine, Oxford and MRC-University of Glasgow Centre for Virus Research).</p>	<input type="checkbox"/>
7.	<p>I agree to gift a stored tumour biopsy, and (if taken) a tumour biopsy taken at relapse for use in research related to this study.</p> <p>I understand that gifting my samples for use in the trial is voluntary and that I am free to withdraw my approval for their use at any time without giving a reason and without my medical treatment or legal rights being affected.</p> <p>I understand that these samples will be marked with my initials, date of birth and trial number, and give permission for these identifiers to be shared with the Central Laboratory (Haematological Malignancy Diagnostic Service, Leeds).</p>	<input type="checkbox"/>
8.	<p>I give permission for my initials, date of birth, sex and NHS/CHI number to be sent to the Cancer Research UK & UCL Cancer Trials Centre. Personal details will be kept strictly confidential and no personal information will be included in the study report or other populations.</p> <p>I give permission for my information to be collected, stored, and used for research at UCL Cancer Trials Centre.</p>	<input type="checkbox"/>
9.	<p>I understand that the information collected about me will be used to support other research in the future, and may be shared anonymously with other researchers.</p>	<input type="checkbox"/>
10.	<p>I understand that my NHS/CHI number may be provided to NHS Digital or other national health registries by Cancer Research UK & UCL Cancer Trials Centre in order to obtain information about my health status.</p>	<input type="checkbox"/>
11.	<p>Women of childbearing potential only:</p> <p>I understand that nivolumab may be harmful to an unborn child, and I agree to use one of the forms of hormonal birth control listed in the Patient Information Sheet, and advise my partner to use condoms, during trial treatment until 6 months after last administration of nivolumab.</p>	<input type="checkbox"/>
	<p>Men with partners of childbearing potential only:</p> <p>I understand that nivolumab may be harmful to an unborn child, and agree to use condoms and advise my partner to use one of the forms of hormonal birth control listed in the Patient Information Sheet during trial treatment until 8 months after last administration of nivolumab.</p>	<input type="checkbox"/>

	If you or your partner are not of childbearing potential, please initial box:	<input type="checkbox"/>
<u>11</u> <u>12.</u>	I agree to take part in the above study.	<input type="checkbox"/>

Superseded

Superseded

OPTIONAL CONSENT – additional samples, future research and pregnancy monitoring

A repeat biopsy for patients who are PET positive after 8 cycles of treatment, donation of samples for future research, [continued follow-up for patient data via registries](#) and pregnancy monitoring are optional.

You can still enter the trial if you do not agree to one or more of the following:

Please initial box if you agree

<p>12 13.</p>	<p>I give permission for doctors to carry out a repeat tumour biopsy if I have a positive PET-CT scan after 8 cycles of nivolumab treatment. I understand that this sample will be sent to the central laboratories (Haematological Malignancy Diagnostic Service & University College London Cancer Institute).</p>	<input type="checkbox"/>
<p>13 14.</p>	<p>I agree that any left-over biopsy material may be provided in anonymised form to other researchers. I understand that their use will be restricted to ethically approved studies. I understand that my samples will be stored at the central laboratories until such time as they are transferred to other researchers.</p> <p>I understand that gifting-donating my samples for use in future research is voluntary and that I am free to withdraw my approval for their use at any time without giving a reason and without my medical treatment or legal rights being affected.</p>	<input type="checkbox"/>
<p>14-15.</p>	<p>I agree that any left-over blood samples may be provided in anonymised form to other researchers. I understand that their use will be restricted to ethically approved studies. I understand that my samples will be stored at the central laboratories until such time as they are transferred to other researchers.</p> <p>I understand that donating my samples for use in future research is voluntary and that I am free to withdraw my approval for their use at any time without giving a reason and without my medical treatment or legal rights being affected.</p>	<input type="checkbox"/>
<p>15-41 6.</p>	<p><i>For women of child bearing potential:</i></p> <p>Should I become pregnant during or after treatment with nivolumab on the trial, I give permission for Cancer Research UK and UCL Cancer Trials Centre, Bristol-Myers Squibb Pharmaceuticals Ltd (the company funding the trial and providing study medication), the study sponsor, University College London and its representatives, regulatory authorities, or from the NHS Trust/Health Board to have access to any of my medical notes and information collected about my pregnancy, including its outcome.</p>	<input type="checkbox"/>

Name of Patient

Date

Signature

Name of person taking consent
(designated responsible person)

Date

Signature

When completed: Take 2 copies. Original and 1 copy to be kept in medical notes and investigator site file, and a copy to be given to the patient.

Data Protection ~~Act 1998~~ Legislation: This research project is registered with the UCL Data Protection Officer as required by the General Data Protection Regulation (EU 2016/679) and UK Data Protection Act 2018 for data protection and the requirements of the Act apply in full. The information collected for this research project, as described in the patient information sheet, ~~held~~ will be used for medical research purposes only which are in the public interest, and will be stored and disposed of in a secure manner.

Superseded