(Form to be on hospital/institution headed paper)

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.	☐
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.	☐
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.	☐
4.	I agree to my GP being informed of my participation in this study.	☐
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.	☐

6.	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. 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. 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 (~~University College London Cancer Institute~~Weatherall Institute of Molecular Medicine, Oxford).	☐
7.	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. 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. 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~~ Laboratory (Haematological Malignancy Diagnostic Service, Leeds ~~& University College London Cancer Institute~~).	☐
8.	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. I give permission for my information to be collected, stored, and used for research at UCL Cancer Trials Centre.	☐
9.	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.	☐
10.	**Women of childbearing potential only:** I understand that nivolumab may be harmful to an unborn trial, 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.	☐
	Men with partners of childbearing potential only: 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.	☐
	If you or your partner are not of childbearing potential, please initial box:	☐

11.	I agree to take part in the above study.	☐

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 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

12.	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).	☐
13.	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. I understand that gifting 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.	☐
14	***For women of child bearing potential:*** 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.	☐

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: This research project is registered for data protection and the requirements of the Act apply in full. The information held will be used for medical research purposes only and will be stored and disposed of in a secure manner.