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

PATIENT REGISTRATION FAX

Number of pages (including cover):
Date:
Name of sender:
Site Name:
Contact telephone number:
Contact email address:
Return fax number:
Pharmacy contact:
Pharmacy contact email address:
Pharmacy contact fax number:

Please fax to **020 7679 9861** or email between
9.00am and 5.00pm

General enquires: 020 7679 9860
E-mail: ctc.animate@ucl.ac.uk

Please note: forms received after 4.00pm may not be processed until the following working day

CANCER RESEARCH UK

Cancer Research UK and UCL Cancer Trials Centre

UCL

General instructions for completing Case Report Forms (CRFs)

Registration Procedure

- To **Register** a patient
  - All inclusion/exclusion criteria must be met
  - All required tests/scans must be completed as per the protocol
  - The **Registration** form should be completed
- Once the above are completed you should **fax** the CTC on **020 7679 9861** or email to **ctc.animate@ucl.ac.uk**—if sent by email, the date of birth and NHS number on page 3 must be redacted and relayed to the CTC via telephone on **0207 679 9860**. The unredacted copy should be sent to UCL CTC by post following registration.
- A member of the CTC trials team will check the eligibility criteria and **Register** the patient if all criteria are met.

Completing Forms

- Ensure all entries are clear, legible and written in black ink
- Avoid the use of abbreviations and acronyms
- The Principal Investigator (PI) is responsible for the accuracy of the data reported on the CRF
- CRFs may only be completed by an individual delegated as responsible by the PI
- CRF Footer section
  - The "completed by" Name should be legible and CRFs should only be completed by individuals on the site delegation log
  - Each CRF should be signed and dated by the person completing the form
  - Do not complete the *For Office Use only* section
- Serious Adverse Events (SAEs) must be faxed within 24 hours of the site being aware of the event to **020 7679 9861**
- If you have any queries or require clarification about completing a CRF please contact a member of the Trial Team on **020 7679 9860**
- Completed CRFs should be sent to the CTC as per section 11.3 of the trial protocol to the address below:

ANIMATE
CR UK & UCL Cancer Trials Centre
90 Tottenham Court Road
London W1T 4TJ

Corrections to entries

- If an error is made draw a single line through the item, then write the correct entry on an appropriate blank space near the original data point on the CRF and initial and date the change.

- **Do NOT**
  - Obscure the original entry by scribbling it out
  - Try to correct/modify the original entry
  - Use Tippex or other correction fluid

For UCL CTC use only: Date Checked: _____ Initials: _____ Date entered: _____ Initials: _____

ANIMATE

Year of Birth | Y | Y | Y | Y |

Patient Initials | | | |

Registration Form (1/11)

Eligibility Checklist

Answers to the following statements must be Yes

	Inclusion Criteria	Yes	No	N/A
1	Age 16 or over			
2	Primary refractory classical Hodgkin lymphoma or classical Hodgkin lymphoma in first relapse			
3	About to receive, receiving, or within 14 days of receiving first 2 cycles of first or second line salvage therapy (4 cycles if receiving treatment with brentuximab vedotin)			
4	Fit for autologous stem cell transplantation			
5	Written informed consent			
6	Willing to comply with the contraceptive requirements of the trial (see section 6.3.4 of the trial protocol)			

Pregnancy Test

		Yes	No	N/A
7	Negative pregnancy test in females of child bearing potential			

If Yes enter date (DD/MM/YYYY) | | | | | | | | |

If N/A please state reason:

Post menopausal for 12 consecutive months ☐

Total abdominal hysterectomy and/ or bilateral oophorectomy ☐

Male ☐

Other Specify below ☐

For UCL CTC use only: Date Checked: _____ Initials: _____ Date entered: _____ Initials: _____

ANIMATE

Year of Birth | Y | Y | Y | Y |

Patient Initials | | | |

Registration Form (2/11)

Eligibility Checklist

Answers to the following statements must be no

	Exclusion Criteria	Yes	No	N/A
1	Nodular lymphocyte predominant Hodgkin lymphoma			
2	Women who are pregnant or breastfeeding			
3	History of colitis, inflammatory bowel disease or pneumonitis			
4	Patients with autoimmune disorders, except patients with vitiligo, diabetes mellitus type 1, hypo- and hyperthyroidism not requiring immunosuppressive therapy			
5	Known active hepatitis B or C infection			
6	Known HIV infection			
7	History of allergy (including severe/life threatening skin reaction) to monoclonal antibodies, anaphylaxis or uncontrolled allergy			
8	Major surgery within 4 weeks prior to registration			
9	Myocardial infarction, unstable angina, coronary artery bypass graft, cerebrovascular accident or transient ischaemic attack within the past 6 months			
10	Non-haematological malignancy within the past 3 years with the exception of (a) adequately treated basal cell carcinoma, squamous cell skin cancer, or thyroid cancer; (b) carcinoma in situ of the cervix or breast; (c) prostate cancer of Gleason grade 6 or less with stable prostate-specific antigen levels; or (d) cancer considered cured by surgical resection or unlikely to impact survival during the duration of the study, such as localised transitional cell carcinoma of the bladder or benign tumours of the adrenal gland or pancreas			

Name of person that has reviewed eligibility (this person must be allocated this role on the trial delegation log and document eligibility in patient medical notes)

For UCL CTC use only: Date Checked: _____ Initials: _____ Date entered: _____ Initials: _____

ANIMATE

Year of Birth Y Y Y Y **Patient Initials** ☐☐☐

Registration Form (3/11)

Registration

This form should be completed only if all criteria on the Eligibility Checklist have been satisfied

Patient Information

Patient Initials ☐☐☐

Site Name ☐

Investigator ☐

Patient Date of Birth (DD/MM/YYYY) ☐☐☐☐☐☐☐☐

Sex ☐ Male ☐ Female

NHS/CHI Number ☐☐☐☐☐☐☐☐☐☐

Details of initial diagnosis

Date of initial diagnosis (DD/MM/YYYY) ☐☐☐☐☐☐☐☐

Stage at initial diagnosis ☐ 1 = I 2 = II 3 = III 4 = IV

Subtype of Hodgkin lymphoma:

☐ Nodular sclerosing ☐ Mixed cellularity

☐ Lymphocyte rich ☐ Lymphocyte depleted

☐ Other, Specify: ☐

B symptoms present at diagnosis?
If yes, please tick all that applybelow: ☐ Yes ☐ No

Drenching night sweats ☐ Fever >38° C ☐ Weight Loss >10% over 6 months ☐

For UCL CTC use only: Date Checked: _____ Initials: _____ Date entered: _____ Initials: _____

ANIMATE

Year of Birth | Y | Y | Y | Y |

Patient Initials | | | |

Registration Form (4/11)

Initial treatment for Hodgkin lymphoma

Initial treatment (please tick one option only)

ABVD	☐	BEACOPP based	☐
ABVD followed by BEACOPP based	☐	ABVD followed by AVD	☐
A2VD (AVD + Brentuximab Vedotin)	☐	Other *(Please specify)*	☐
			☐

Did the patient receive radiotherapy?	☐	Yes	☐	No		
If yes, was relapse within the irradiated field?	☐	Yes	☐	No	☐	N/A

For UCL CTC use only: Date Checked: _____ Initials: _____ Date entered: _____ Initials: _____

ANIMATE

Year of Birth Y Y Y Y

Patient Initials ☐ ☐ ☐

Registration Form (5/11)

Scans during initial treatment for Hodgkin lymphoma

Interim PET-CT scan during first line treatment

Was an interim PET-CT scan performed? ☐ Yes ☐ No
If yes, please specify details below:

Date of interim PET-CT scan (DD/MM/YYYY) ☐☐☐☐☐☐☐☐

What was the result of the interim PET-CT scan? ☐ Negative Deauville score 1-3 ☐ Positive Deauville score 4-5

End of first line treatment scan

What type of end of treatment scan was performed? ☐ PET-CT ☐ CT ☐ Not done ☐ Other
Please specify:

Date of end of treatment scan (DD/MM/YYYY) ☐☐☐☐☐☐☐☐

PET-CT
- ☐ Complete Metabolic Response (CMR)
- ☐ Partial Metabolic Response (PMR)
- ☐ No Metabolic Response (NMR)
- ☐ Progressive Metabolic Disease (PMD)

Please see appendix 3 of the trial protocol for guidance

CT
- ☐ Complete Response (CR)
- ☐ Partial Response (PR)
- ☐ Stable Disease (SD)
- ☐ Progressive Disease (PD)

For UCL CTC use only: Date Checked: _____ Initials: _____ Date entered: _____ Initials: _____

ANIMATE

Year of Birth Y Y Y Y

Patient Initials ☐ ☐ ☐

Registration Form (6/11)

Relapse after initial treatment for Hodgkin lymphoma

Details of relapse

Date of relapse diagnosis (DD/MM/YYYY) ☐☐ ☐☐ ☐☐☐☐ ☐ N/A - Primary refractory

Stage at relapse ☐ 1 = I 2 = II 3 = III 4 = IV

B symptoms present at relapse? ☐ Yes ☐ No
If yes, please tick all that apply below:

Drenching night sweats ☐

Fever >38° C ☐

Weight Loss >10% over 6 months ☐

Was the patient anaemic at relapse? ☐ Yes ☐ No
Hb less than lower limit of normal

Number of extranodal sites at relapse? ☐☐

For UCL CTC use only: Date Checked: _____ Initials: _____ Date entered: _____ Initials: _____

ANIMATE

Year of Birth Y Y Y Y

Patient Initials ☐ ☐ ☐

Registration Form (7/11)

Treatment for relapsed/refractory Hodgkin lymphoma

Treatment at relapse (please tick one option only)

How many lines of salvage has the patient received? ☐

1 = currently or about to receive first line salvage
Complete page 7 then go on to page 9
2 = currently or about to receive second line salvage
Complete pages 7 and 8

First line salvage

Type of treatment *(Tick as applicable)*

ESHAP	☐	IGEV	☐
Brentuximab Vedotin	☐	IVE	☐
ICE	☐	GDP	☐
DHAP	☐	Other *(Please specify)*	☐

☐

Number of cycles received so far ☐

Date of response assessment if done (DD/MM/YYYY) ☐☐☐☐☐☐☐☐ OR Not due yet ☐

Response to first line salvage

PET-CT

☐	Complete Metabolic Response (CMR)	☐	Partial Metabolic Response (PMR)
☐	No Metabolic Response (NMR)	☐	Progressive Metabolic Disease (PMD)

Please see appendix 3 of the trial protocol for guidance

CT

☐	Complete Response (CR)	☐	Partial Response (PR)
☐	Stable Disease (SD)	☐	Progressive Disease (PD)

For UCL CTC use only: Date Checked: _____ Initials: _____ Date entered: _____ Initials: _____

ANIMATE

Year of Birth | Y | Y | Y | Y |

Patient Initials | | | |

Registration Form (8/11)

Treatment for relapsed/refractory Hodgkin lymphoma: second line salvage

Complete this page only if patient is receiving or about to receive second line salvage

Type of treatment *(Tick as applicable)*

ESHAP	☐	IVE	☐
Brentuximab Vedotin	☐	GDP	☐
ICE	☐	Mini-BEAM/LEAM	☐
DHAP	☐	Gem-P	☐
IGEV	☐	Other *(Please specify)*	☐

Number of cycles received so far ☐

For UCL CTC use only: Date Checked: _____ Initials: _____ Date entered: _____ Initials: _____

ANIMATE

Year of Birth | Y | Y | Y | Y |

Patient Initials | | | |

Registration Form (9/11)

Medical history (excluding Hodgkin lymphoma)

Enter details of all significant medical conditions, past or present, e.g. malignancies, autoimmune disorders, colitis, inflammatory bowel disease hepatitis, pneumonitis, cardiac conditions, HIV, allergies (including drug allergies). Please check eligibility list in trial protocol.
Where a condition is continuing and symptomatic (e.g. uncontrolled hypertension), please insert the CTCAE v5.0 grade.
If condition is ongoing enter C (Continuing) as End Date

Any significant medical history? ☐ Yes ☐ No *If Yes specify below:*

	Condition Please record all significant conditions Use the CTCAE v5.0 adverse event name where applicable	**Status** Resolved/ Asymptomatic = 0 Continuing = 1	**Onset Date** (DD/MM/YYYY)	**End Date** (DD/MM/YYYY)
1				
2				
3				
4				
5				
6				
7				
8				
9				
10				
11				
12				
13				
14				
15				

For UCL CTC use only: Date Checked: _____ Initials: _____ Date entered: _____ Initials: _____

ANIMATE

Year of Birth Y Y Y Y

Patient Initials ☐☐☐

Registration Form (10/11)

Informed consent

Date patient information sheet given (DD/MM/YYYY) ☐☐☐☐☐☐☐☐

Date consent form signed (DD/MM/YYYY) ☐☐☐☐☐☐☐☐

Version number of the patient information sheet given to patient ☐.☐

Version number of the consent form signed ☐.☐

Has patient initialled all mandatory boxes? ☐ Yes ☐ No

Has patient signed and personally dated the ICF? ☐ Yes ☐ No

Name of person taking consent: (must be on delegation log and the consent process documented in patient medical notes) ☐

Has person taking consent signed and dated the ICF (on same day as patient)? ☐ Yes ☐ No

Has the patient agreed for a repeat tumour biopsy to be taken if they have a positive PET-CT scan after 8 cycles of nivolumab treatment? ☐ Yes ☐ No

Has the patient agreed to donate surplus biopsy material for use in future research? ☐ Yes ☐ No

Has the patient agreed to donate left-over blood samples for use in future research? ☐ Yes ☐ No

For women of child bearing potential:

Has the patient agreed for UCL CTC and other parties to have access to pregnancy information should they become pregnant? ☐ Yes ☐ No ☐ N/A

Completed by: ☐

Signature: ☐

CRFs should only be completed by appropriately qualified personnel detailed on the site delegation log

Date completed: D D M M Y Y Y Y ☐☐☐☐☐☐☐☐

For UCL CTC use only: Date Checked: _____ Initials: _____ Date entered: _____ Initials: _____

ANIMATE

Year of Birth | Y | Y | Y | Y |

Patient Initials | | | |

Registration Form (11/11)

For CTC Office Use Only

Consented by staff member on delegation log ☐

Eligibility confirmed by trial Investigator on delegation log ☐

Eligibility confirmed by CTC staff member ☐

Trial Information

Trial Number **A N M** – | | | |

Date of Registration (DD/MM/YYYY) | | | | | | | | |

Registered by: _____ Signature: _____

Please return to: ANIMATE Trial Coordinator, CR UK & UCL Cancer Trials Centre, 90 Tottenham Court Road, London, W1T 4TJ

For UCL CTC use only: Date Checked: _____ Initials: _____ Date entered: _____ Initials: _____

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

POST-SALVAGE TREATMENT FAX

Number of pages (including cover):
Date:
Name of sender:
Site Name:
Contact telephone number:
Contact email address:
Return fax number:
Pharmacy contact:
Pharmacy contact email address:
Pharmacy contact fax number:

Please fax to **020 7679 9861** or fax to **ctc.animate@ucl.ac.uk**
between 9.00am and 5.00pm

General enquires: 020 7679 9860
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Trial Number A N M – | | |

Patient Initials | | |

Post-Salvage Treatment Form (1/13)

PET- CT Scan

(post 2 cycles of first or second line salvage therapy)

Section A

Date of scan (DD/MM/YYYY) | | | | | | | | |

Contrast-enhanced CT Scan

(if feasible, to be performed at same imaging session as PET-CT scan)

Date of scan (DD/MM/YYYY) | | | | | | | | |

What was the result of the PET-CT central review? ☐ Negative Deauville score 1-3 ☐ Positive Deauville score 4-5

If the end of salvage PET-CT scan (PET0)was positive (Deauville 4-5), please complete sections A and B.
If the result was negative (Deauville 1-3) then please complete section A only.

Archival tumour biopsy

Has the patient's biopsy been sent for central review? ☐ Yes ☐ No

Specify reason below:

Specify biopsy timepoint ☐ Diagnosis ☐ Relapse

Date of Biopsy (DD/MM/YYYY) | | | | | | | | |

Date sent to HMDS (DD/MM/YYYY) | | | | | | | | |

Hospital Block/ Sample Number | | | | | | | | | | |

For UCL CTC use only: Date Checked: _____ Initials: _____ Date entered: _____ Initials: _____

ANIMATE

Trial Number A N M – ☐☐☐ Patient Initials ☐☐☐

Post-Salvage Treatment Form (2/13)

Salvage Therapy

Section A

How many lines of salvage did the patient receive? ☐ One ☐ Two

First line salvage

☐ If full details of first line salvage (including response) already reported on Registration Form, tick this box and move to the next page.

Type of treatment *(Tick as applicable)*

ESHAP	☐	IGEV	☐
Brentuximab Vedotin	☐	IVE	☐
ICE	☐	GDP	☐
DHAP	☐	Other *(Please specify)*	☐

☐

Number of cycles received ☐

Date of last dose of first line salvage treatment (DD/MM/YYYY) ☐☐/☐☐/☐☐☐☐

Date of response assessment (DD/MM/YYYY) ☐☐/☐☐/☐☐☐☐

PET-CT

☐	Complete Metabolic Response (CMR)	☐	Partial Metabolic Response (PMR)
☐	No Metabolic Response (NMR)	☐	Progressive Metabolic Disease (PMD)

Please see appendix 3 of the trial protocol for guidance

CT

☐	Complete Response (CR)	☐	Partial Response (PR)
☐	Stable Disease (SD)	☐	Progressive Disease (PD)

For UCL CTC use only: Date Checked: _____ Initials: _____ Date entered: _____ Initials: _____

ANIMATE

Trial Number A N M – ☐☐☐ Patient Initials ☐☐☐

Post-Salvage Treatment Form (3/13)

Salvage Therapy

Section A

Second line salvage

Type of treatment *(Tick as applicable)* OR N/A ☐

ESHAP	☐	IVE	☐
Brentuximab Vedotin	☐	GDP	☐
ICE	☐	Mini-BEAM/LEAM	☐
DHAP	☐	Gem-P	☐
IGEV	☐	Other *(Please specify)*	☐

Number of cycles given ☐

☐

Date of last dose of second line salvage treatment ☐☐☐☐☐☐☐☐

For UCL CTC use only: Date Checked: _____ Initials: _____ Date entered: _____ Initials: _____

ANIMATE

Trial Number A N M – ☐☐☐ Patient Initials ☐☐☐

Post-Salvage Treatment Form (4/13)

Did the patient receive Radiotherapy as part of salvage? ☐ Yes ☐ No

If yes:

Date radiotherapy started (DD/MM/YYYY) ☐☐☐☐☐☐☐☐

Date radiotherapy finished (DD/MM/YYYY) ☐☐☐☐☐☐☐☐

Completed by:

Signature:

CRFs should only be completed by appropriately qualified personnel detailed on the site delegation log

Date completed: D D M M Y Y Y Y

Please return to: ANIMATE Trial Coordinator, CR UK & UCL Cancer Trials Centre, 90 Tottenham Court Road, London, W1T 4TJ

For Office use only

For UCL CTC use only: Date Checked: _____ Initials: _____ Date entered: _____ Initials: _____

ANIMATE

Trial Number A N M – ☐☐☐ Patient Initials ☐☐☐

Post-Salvage Treatment Form (5/13)

Eligibility Checklist

Section B

Answers to the following statements must be Yes

	Inclusion Criteria	Yes	No	N/A
1	Has received 2 cycles of first or second line salvage chemotherapy, (4 cycles if receiving treatment with brentuximab vedotin)			
2	PET positive (Deauville score 4 or 5) after 2 cycles of first or second line salvage chemotherapy (4 cycles if receiving treatment with brentuximab vedotin)			
3	Fit for further salvage chemotherapy			
4	ECOG performance status 0-1			
5	Creatinine clearance >30ml/min calculated by Cockcroft-Gault formula			
6	Bilirubin <1.5 x ULN, ALT/AST <2.5 x ULN			
7	Adequate bone marrow function (Hb >80g/l. Platelets >50 x 10^9/l, neutrophils >1.0 x10^9/l			

Pregnancy Test

		Yes	No	N/A
8	Negative pregnancy test in females of child bearing potential			

If Yes enter date (DD/MM/YYYY) ☐☐☐☐☐☐☐☐

If N/A please state reason:

Post menopausal for 12 consecutive months ☐

Total abdominal hysterectomy and/ or bilateral oophorectomy ☐

Male ☐

Other Specify below ☐

For UCL CTC use only: Date Checked: _____ Initials: _____ Date entered: _____ Initials: _____

ANIMATE

Trial Number A N M – ☐☐☐ Patient Initials ☐☐☐

Post-Salvage Treatment Form (6/13)

Eligibility Checklist

Answers to the following statements must be no ***Section B***

	Exclusion Criteria	Yes	No
1	Deauville score 1-3 after 2 cycles of first or second line salvage chemotherapy (4 cycles if receiving treatment with brentuximab vedotin)		
2	Positive serology for hepatitis B or C (unless (a) hepatitis B positive due to vaccination (HBsAb positive, all other tests negative) or (b) past hepatitis B infection with low risk of reactivation (HBcAb positive & HBcAb positive, other tests negative—PI approval needed)		
3	Active infection requiring systematic therapy		
4	Ongoing requirement for immunosuppressive therapy, apart from inhaled, intranasal, topical corticosteroids or systemic corticosteroids at low doses (≤10mg prednisolone per day, or the equivalent)		
5	Chemo- or radiotherapy or corticosteroids at a dose of more than 10mg per day prednisolone or equivalent within 14 days prior to response PET-CT. NOTE: corticosteroids can be used AFTER a positive PET-CT scan for symptomatic disease but must be weaned to a dose of prednisolone ≤10mg/day or less (or equivalent) at least 7 days prior to starting nivolumab		
6	Treatment with any investigational agent within 28 days prior to planned start of nivolumab		
7	Ongoing grade 2-4 non-haematological toxicities related to prior Hodgkin lymphoma treatments, with the exception of alopecia and grade 2 fatigue		
8	Pregnant or breastfeeding women		

Name of person that has reviewed eligibility (this person must be allocated this role on the trial delegation log)

Hepatitis Serology

Date of Test (DD/MM/YYYY):	Positive	Negative	Not Done
Hep B surface antigen (HBsAg)			
Hep B surface antibody (HBsAb)	**		*
Hep B core antibody (HBcAb)	**		
Hep B antibodies or Hep B DNA (HBV DNA)			
Hep C antibodies or Hep C DNA (HCV DNA)			

* HBsAb testing only required if standard of care locally

**Serology results reviewed, and suitability for treatment confirmed, by treating clinician (name):

DD/MM/YYYY ☐☐☐☐☐☐☐☐

For UCL CTC use only: Date Checked: _____ Initials: _____ Date entered: _____ Initials: _____

ANIMATE

Trial Number A N M – | | |

Patient Initials | | |

Post-Salvage Treatment Form (7/13)

Post-salvage assessment

Section B

Date of Assessment (DD/MM/YYYY) | | | | | | | | |

Weight (kg) | | | | . | |

ECOG Performance Status | |

Haematology *(to be performed at least 3 weeks post completion of salvage)*

Date of Haematology (DD/MM/YYYY) | | | | | | | | |

Haemoglobin g/L | | | | . | |

Platelets x 10^9/L | | | |

Absolute Neutrophil Count (ANC) x10^9/L | | . | |

Absolute Lymphocyte Count (ALC) x10^9/L | | . | |

White Blood Cell (WBC) Count x10^9/L | | . | |

For UCL CTC use only: Date Checked: _____ Initials: _____ Date entered: _____ Initials: _____

ANIMATE

Trial Number A N M – ☐☐☐ Patient Initials ☐☐☐

Post-Salvage Treatment Form (8/13)

Biochemistry (*to be performed at least 3 weeks post completion of salvage)*

Section B

Date of Biochemistry (DD/MM/YYYY) ☐☐☐☐☐☐☐☐

U&Es	**Test Result**		
Sodium mmol/L	☐☐☐☐	Magnesium mmol/L	☐☐.☐☐
Potassium mmol/L	☐☐.☐☐	Calcium mmol/L	☐☐.☐☐
Urea mmol/L	☐☐.☐☐	Urate mmol/L	☐☐.☐☐
Creatinine µmol/L	☐☐☐.☐		
Creatinine Clearance ml/min (Cockcroft-Gault)	☐☐☐.☐		

Liver Function Tests	**Test Result**	**Upper Limit of Normal (ULN)**
Albumin g/L	☐☐☐	
Bilirubin µmol/L	☐☐☐	☐☐☐
Alk. Phosphatase IU/L	☐☐☐☐	
Aspartate Transaminase (AST) IU/L	☐☐☐☐	☐☐☐☐
OR		
Alanine Transaminase (ALT) IU/L	☐☐☐☐	☐☐☐☐
Lactate dehydrogenase (LDH) IU/L	☐☐☐☐	
Glucose mmol/L	☐☐.☐☐	

For UCL CTC use only: Date Checked: _____ Initials: _____ Date entered: _____ Initials: _____

ANIMATE

Trial Number A N M – | | |

Patient Initials | | |

Post-Salvage Treatment Form (9/13)

Section B

Autoimmune tests

Date of Assessment (DD/MM/YYYY) | | | | | | | | |

Amylase U/L | | |

Lipase U/L | | |

ACTH ng/L | | |

Thyroid function tests

Date of Assessment (DD/MM/YYYY) | | | | | | | | |

TSH mIU/L | | | . | |

Free T4 pmol/L | | | . | |

Free T3 pmol/L | | | . | | To be taken if TSH / T4 abnormal otherwise please tick this box for N/A ☐

Lung function tests

Date of Assessment (DD/MM/YYYY) | | | | | | | | |

Spirometry

FEV1/FVC% | | | | FEV1% of normal | | | |

Diffusion Capacity (DLCO/TLCO)

DLCO ml/min/mmHg | | | . | | Tick if not done ☐

or % of normal | | |

TLCO mmol/kPA/min | | | . | | Tick if not done ☐

For UCL CTC use only: Date Checked: _____ Initials: _____ Date entered: _____ Initials: _____

ANIMATE

Trial Number A N M – | | | |

Patient Initials | | |

Post-Salvage Treatment Form (10/13)

Section B

ECG

Date of ECG (DD/MM/YYYY) | | | | | | | | |

Result | |

1 = Normal
2 = Abnormal - please provide details & results of echocardiogram below
3 = Abnormal, not clinically significant

Specify Abnormality

QTc interval (ms) | | |

Echocardiogram (if required)

Date of Echocardiogram (DD/MM/YYYY) | | | | | | | | |

N/A | |

Result | |

1 = Normal
2 = Abnormal - please provide details below
3 = Abnormal, not clinically significant

Specify Abnormality

LVEF | |

1 = ≤ 50%
2 = > 50%

For UCL CTC use only: Date Checked: _____ Initials: _____ Date entered: _____ Initials: _____

ANIMATE

Trial Number A N M – | | |

Patient Initials | | |

Post-Salvage Treatment Form (11/13)

Baseline AEs

Section B

Enter details of all significant conditions that are continuing or have developed post-registration.
Where a condition is continuing and symptomatic (e.g. uncontrolled hypertension), please insert the CTCAE v5.0 grade.
If condition is ongoing enter C (Continuing) as End Date

Any significant new medical history or baseline symptoms? ☐ Yes ☐ No *If Yes specify below:*

	Condition please record all significant conditions Use the CTCAE adverse event name where Applicable, please see CTCAE v5.0 for guidance	**Status** Resolved/ Asymptomatic = 0 Continuing = 1	**Onset Date** (DD/MM/YYYY)	**End Date** (DD/MM/YYYY)	**Specify grade of Adverse Event**	**Treatment Ongoing** No = 0 Yes = 1*
1						
2						
3						
4						
5						
6						
7						
8						
9						
10						
11						
12						
13						
14						
15						

* If yes, please provide details on page 11.

For UCL CTC use only: Date Checked: _____ Initials: _____ Date entered: _____ Initials: _____

ANIMATE

Trial Number A N M – | | | |

Patient Initials | | |

Post-Salvage Treatment Form (12/13)

Additional Treatment

Section B

Has the patient taken any additional medication within 30 days prior to this visit? ☐ Yes ☐ No *If Yes specify below:*

	Start Date (DD/MM/YYYY)	End Date (DD/MM/YYYY)	Generic Drug Name	Treatment Ongoing Yes = 1 No = 0	Indication Use the CTCAE v5.0 adverse event name where applicable
1					
2					
3					
4					
5					
6					
7					
8					
9					
10					
11					
12					
13					
14					
15					
16					
17					
18					

Completed by:

Signature:

CRFs should only be completed by appropriately qualified personnel detailed on the site delegation log

Date completed: D D M M Y Y Y Y

ANIMATE

Trial Number A N M – | | |

Patient Initials | | |

Post-Salvage Treatment Form (13/13)

For CTC Office Use Only

Date Eligibility for Treatment Confirmed | | | | | | | | |

Eligibility for treatment confirmed by:

Signature:

For UCL CTC use only: Date Checked: _____ Initials: _____ Date entered: _____ Initials: _____

ANIMATE

Trial Number A N M – ☐☐☐ Patient Initials ☐☐☐

Treatment Form (1/5)

Cycle No. ☐

Pre-treatment assessment

Pregnancy Test *(to be performed within 24 hrs prior to starting nivolumab at cycles 1, 3 , 5 and 7)*

N/A this cycle ☐

	Yes	No	N/A
Negative pregnancy test in females of child bearing potential			

If Yes enter date (DD/MM/YYYY) ☐☐☐☐☐☐☐☐

If N/A please state reason:

Post menopausal for 12 consecutive months ☐

Total abdominal hysterectomy and/ or bilateral oophorectomy ☐

Male ☐

Other Specify below ☐

Haematology *(to be performed within 3 days prior to starting each cycle)*

Date of Haematology (DD/MM/YYYY) ☐☐☐☐☐☐☐☐

Haemoglobin g/L ☐☐☐.☐☐

Platelets x 10^9/L ☐☐☐☐

Absolute Neutrophil Count (ANC) x10^9/L ☐☐.☐☐

Absolute Lymphocyte Count (ALC) x10^9/L ☐☐.☐☐

White Blood Cell (WBC) Count x10^9/L ☐☐☐.☐☐

For UCL CTC use only: Date Checked: _____ Initials: _____ Date entered: _____ Initials: _____

ANIMATE

Trial Number A N M – ☐☐☐ Patient Initials ☐☐☐

Treatment Form (2/5)

Cycle No. ☐

Biochemistry *(to be performed within 3 days prior to the start of each cycle)*

Date of Biochemistry (DD/MM/YYYY) ☐☐☐☐☐☐☐☐

U&Es	Test Result		Test Result
Sodium mmol/L	☐☐☐☐	Magnesium mmol/L	☐☐.☐☐
Potassium mmol/L	☐☐.☐☐	Calcium mmol/L	☐☐.☐☐
Urea mmol/L	☐☐.☐☐	Urate mmol/L	☐☐.☐☐
Creatinine µmol/L	☐☐☐.☐		

Liver Function Tests	Test Result
Albumin g/L	☐☐☐
Bilirubin µmol/L	☐☐☐
Alk. Phosphatase IU/L	☐☐☐☐
Aspartate Transaminase (AST) IU/L	☐☐☐☐
OR	
Alanine Transaminase (ALT) IU/L	☐☐☐☐
Lactate dehydrogenase (LDH) IU/L	☐☐☐☐
Glucose mmol/L	☐☐.☐☐

For UCL CTC use only: Date Checked: _____ Initials: _____ Date entered: _____ Initials: _____

ANIMATE

Trial Number A N M – ☐☐☐ Patient Initials ☐☐☐

Treatment Form (3/5)

Cycle No. ☐

Autoimmune tests *(to be performed within 3 days prior to the start of each cycle)*

Date of Assessment (DD/MM/YYYY) ☐☐☐☐☐☐☐☐

Amylase IU/L ☐☐☐

Lipase IU/L ☐☐☐

ACTH ng/L ☐☐☐

Thyroid function tests *(to be performed within 3 days prior to the start of cycles 1, 4 and 7)*

Date of Assessment (DD/MM/YYYY) ☐☐☐☐☐☐☐☐ N/A this cycle ☐

TSH mIU/L ☐☐.☐☐

Free T4 pmol/L ☐☐.☐☐

Free T3 pmol/L ☐☐.☐☐ To be taken if TSH / T4 abnormal otherwise please tick this box for N/A ☐

Oxygen saturation *(to be carried out each cycle on the day of nivolumab administration)*

Date of Assessment (DD/MM/YYYY) ☐☐☐☐☐☐☐☐

Oxygen Saturation % ☐☐☐

For UCL CTC use only: Date Checked: _____ Initials: _____ Date entered: _____ Initials: _____

ANIMATE

Trial Number A N M – ☐☐☐ Patient Initials ☐☐☐

Treatment Form (4/5)

Cycle No. ☐

Trial Treatment

Drug	Date given (DD/MM/YYYY)	Dose given	Units	Route	Days	Was there a dose delay ? 1 = Yes 0 = No If yes, please specify below
Nivolumab			**mg**	**IV**	**1**	

If dose was not 240mg, please specify reason:

Drug	Reason for Delay (use code, see below)	How many days was treatment delayed for?	Specify AE/SAE Terms/Other reason (applicable for codes 1, 2, & 5 - use box below if more space needed)
Nivolumab			

1= Adverse event
2= Serious adverse event
3= Patient decision
4= Withdrawal of consent
5= Other (specify)

If patient has stopped treatment completely, please fill in the Treatment Summary form and/or if patient has experienced an SAE, please submit an SAE report form.

For UCL CTC use only: Date Checked: _____ Initials: _____ Date entered: _____ Initials: _____

ANIMATE

Trial Number A N M – | | |

Patient Initials | | |

Treatment Form (5/5)

Cycle No. |

Blood sample for translational research *(to be taken at the beginning of cycles 1, 2, 4, 6 and 8)*

Date sample taken (DD/MM/YYYY) | | | | | | | | |

N/A this cycle |

Date sample sent to central laboratory (DD/MM/YYYY) | | | | | | | | |

Sample not taken |

Please give reason for not taking sample:

PET- CT Scan

(to be carried out on days 11-13 of cycles 4 and 8. If patient stops treatment during cycles 5-7, scan must be carried out at least 11-13 days after last treatment)

Date of scan (DD/MM/YYYY) | | | | | | | | |

N/A this cycle |

Date scan sent for central review (DD/MM/YYYY) | | | | | | | | |

Contrast-enhanced CT Scan

(if feasible, to be performed at same imaging session as PET-CT scan)

Date of scan (DD/MM/YYYY) | | | | | | | | |

N/A this cycle |

Date scan sent for central review (DD/MM/YYYY) | | | | | | | | |

Completed by:

Signature:

CRFs should only be completed by appropriately qualified personnel detailed on the site delegation log

Date completed: D D M M Y Y Y Y | | | | | | | |

For UCL CTC use only: Date Checked: _____ Initials: _____ Date entered: _____ Initials: _____

Additional instructions for completing forms

Treatment Form

The Treatment Form is used to record all trial treatment chemotherapy administered to the patient. Each Patient may receive up to 8 cycles of nivolumab (each cycle being 14 days in length)

Completing the form

- This form should be submitted within 2 weeks of the end of each cycle.
- Please remember to review the **Rolling Adverse Event Form** at the end of each cycle and send updates as necessary. The cover page must be completed and sent each cycle even if there have been no new AEs.

Specific Fields

- *Treatment doses (page 4)*
  - *Dose* — the patient is to be administered a flat dose of 240mg on day 1 of each cycle.
  - *Was there a dose delay? - Y = 1 / N = 0* – If there was a delay enter 1 for Yes in the box, if the drug was administered as planned enter N

- *Was the full dose given? (page 4)*
  - A flat dose of 240mg is to be administered. However, it is possible that an infusion may be stopped prematurely due to an adverse reaction. Please specify in the box provided when this occurs and record the dose received by the patient during infusion.

- *Delays/Omission (page 4)*
  - *Drug*– Nivolumab is the only IMP on this trial.
  - *Reason for delay*– the appropriate code should be entered. Further detail should be provided as required (see below)
  - *Treatment delay*—please specify number of days treatment was delayed where applicable.
  - *Specify Adverse Event/SAE Term(s) / Other Reason-* this should be completed where codes 1,2 or 5 have been entered in the 'reason for delay' column. If more than one AE/SAE contributed to the delay, please enter all relevant terms as a list. If you need more space, please use the box at the bottom of the page.

If you have any questions about how to complete this form please contact the ANIMATE Trial Coordinator on:
020 7679 9860

ANIMATE

Trial Number A N M – | | | |

Patient Initials | | |

Treatment Summary Form (1/1)

Treatment Summary

Number of cycles given

Date of last nivolumab administration (DD/MM/YYYY)

Date of decision to stop treatment (DD/MM/YYYY)

Please submit the Nivolumab patient accountability logs with this form

Specify the reason for stopping trial treatment
Tick one box only

- ☐ Completed 8 cycles
- ☐ PET negative after 4 cycles
- ☐ Disease Progression *please complete disease progression form*
- ☐ Serious Adverse Event (SAE) *including autoimmune events and death, Please complete SAE report form and/or death form if applicable*
- ☐ Unacceptable Non-Serious Adverse Event(s) *please specify event name, Grade and report on adverse event form, see CTCAE v5 for guidance*
  - Event term(s) ____ Grade ☐
- ☐ Intercurrent illness preventing further treatment
  - Event term ____ Grade ☐
- ☐ Clinician decision (not Adverse Event related)
- ☐ Patient decision
  - Has the patient withdrawn consent for follow up? ☐ Yes ☐ No
  - *If so, please complete Lost to Follow Up Form*
- ☐ Other *please specify reason:* ____

Completed by:

Signature:

CRFs should only be completed by appropriately qualified personnel detailed on the site delegation log

Date completed: D D M M Y Y Y Y

For UCL CTC use only: Date Checked: _____ Initials: _____ Date entered: _____ Initials: _____

Additional instructions for completing forms

Treatment Summary Form

The Treatment Summary Form is used to capture a summary of the treatment administered to a patient.

Completing the form

- This form should be submitted within two weeks of the decision to stop treatment (with the Treatment CRF for the last cycle given).
- If the patient stopped trial treatment early for any reason, details should be recorded on this form.
- If a patient withdraws consent to follow up please complete the Lost to Follow Up Form in addition to the Treatment Summary Form
- Please submit the Nivolumab patient accountability logs with this form.

Specific Fields

- *Specify the reason for Withdrawal (if applicable)*- only one box should be ticked
  - *Unacceptable Adverse Event*

    - Grade should be entered where applicable (ensure all AEs are entered on the Adverse Event form and if an SAE is observed fax through and SAE Report Form to the CTC). Please see CTCAE v5 for guidance.

If you have any questions about how to complete this form please contact the ANIMATE Trial Coordinator on:
020 7679 9860

ANIMATE

Trial Number A N M – | | |

Patient Initials | | |

Follow Up Form (1/5) (for patients who received nivolumab)

Month | | To be used at months 1-12

Pregnancy Test *(at follow up months 1, 2 and 3)*

	Yes	No	N/A
Negative pregnancy test in females of child bearing potential			

If Yes enter date | | | | | | | | | | N/A this visit |

If N/A please state reason:

- Post menopausal for 12 consecutive months
- Total abdominal hysterectomy and/ or bilateral oophorectomy
- Male
- Other Specify below

Haematology *(to be performed at 1, 2, 3, 6, 9 & 12 months post treatment visits)*

Date of Haematology (DD/MM/YYYY) | | | | | | | | |

Haemoglobin g/L | | | | • | | |

Platelets x 10^9/L | | | | |

Absolute Neutrophil Count (ANC) x10^9/L | | | • | | |

Absolute Lymphocyte Count (ALC) x10^9/L | | | • | | |

White Blood Cell (WBC) Count x10^9/L | | | | • | | |

For UCL CTC use only: Date Checked: _____ Initials: _____ Date entered: _____ Initials: _____

ANIMATE

Trial Number A N M – ☐☐☐ Patient Initials ☐☐☐

Follow Up Form (2/5) (for patients who received nivolumab)

Month ☐☐ To be used at months 1-12

Biochemistry *(to be performed at 1,2, 3, 6, 9 & 12 months post treatment visits)*

Date of Biochemistry (DD/MM/YYYY) ☐☐/☐☐/☐☐☐☐

U&Es	Test Result		Test Result
Sodium mmol/L	☐☐☐☐	Magnesium mmol/L	☐☐.☐☐
Potassium mmol/L	☐☐.☐☐	Calcium mmol/L	☐☐.☐☐
Urea mmol/L	☐☐.☐☐	Urate mmol/L	☐☐.☐☐
Creatinine µmol/L	☐☐☐.☐		

Liver Function Tests	Test Result
Albumin g/L	☐☐☐
Bilirubin µmol/L	☐☐☐
Alk. Phosphatase IU/L	☐☐☐☐
Aspartate Transaminase (AST)	☐☐☐☐
OR	
Alanine Transaminase (ALT) IU/L	☐☐☐☐
Lactate dehydrogenase (LDH) IU/L	☐☐☐☐
Glucose mmol/L	☐☐.☐☐

For UCL CTC use only: Date Checked: _____ Initials: _____ Date entered: _____ Initials: _____

ANIMATE

Trial Number A N M – | | |

Patient Initials | | |

Follow Up Form (3/5) (for patients who received nivolumab)

Month | | To be used at months 1-12

Autoimmune tests *(to be performed at 1, 2 and 3 months post-treatment follow up visits)*

Date of Assessment (DD/MM/YYYY) | | | | | | | | | N/A this visit ☐

Amylase IU/L | | |

Lipase IU/L | | |

ACTH ng/L | | |

Thyroid function tests *(to be performed at 1, 2 and 3 months post-treatment follow up visits)*

Date of Assessment (DD/MM/YYYY) | | | | | | | | | N/A this visit ☐

TSH mIU/L | | | • | |

Free T4 pmol/L | | | • | |

Free T3 pmol/L | | | • | | To be taken if TSH / T4 abnormal otherwise please tick this box for N/A ☐

Lung function tests *(to be performed 10 (±2) days and 12 months post-treatment)*

Date of Assessment (DD/MM/YYYY) | | | | | | | | | N/A this visit ☐

Spirometry

FEV1/FVC% | | | FEV1% of normal | | |

Diffusion Capacity (DLCO/TLCO)

DLCO ml/min/mmHg | | • | | | Tick if not done ☐

or

% of normal | | |

TLCO mmol/kPA/min | | • | | | Tick if not done ☐

For UCL CTC use only: Date Checked: _____ Initials: _____ Date entered: _____ Initials: _____

ANIMATE

Trial Number A N M – | | |

Patient Initials | | |

Follow Up Form (4/5) (for patients who received nivolumab)

Month | | To be used at months 1-12

Further Treatment

Has the patient started new treatment for Hodgkin lymphoma? ☐ Yes ☐ No

Please complete and send a New Treatment form

Adverse Event Assessment *(complete at months 1, 2 and 3 unless patient has started a new treatment for Hodgkin lymphoma)*

Date of assessment (DD/MM/YYYY) | | | | | | | | | N/A this visit ☐

Has the rolling AE form been updated and submitted to UCL CTC? ☐ Yes ☐ No

Assessment for late toxicity of nivolumab

(complete at follow up months 6, 9 and 12)

Date of assessment (DD/MM/YYYY) | | | | | | | | | N/A this visit ☐

Has the patient experienced any late toxicity attributed to nivolumab?

If yes, please specify below, including any treatment: ☐ Yes ☐ No

Please continue to report AESI/SAEs up to 5 months post nivolumab treatment, or later if considered a late effect of nivolumab (see protocol section 12.2.2 for guidance)

FOR UCL CTC USE ONLY:

SAE number: _____

ANIMATE

Trial Number A N M – | | | |

Patient Initials | | |

Follow Up Form (5/5) (for patients who received nivolumab)

Month | | To be used at months 1-12

Remission status

Date of assessment (DD/MM/YYYY) | | | | | | | | |

Has the patient relapsed or progressed?
*If yes, please complete a **disease progression form** and send biopsy sample if taken. Details of the biopsy should be recorded on the*

☐ Yes ☐ No

Biopsy—patients who are PET positive after 8 cycles

(To be performed at end of treatment if PET positive after 8 cycles and patient has consented)

Date of biopsy (DD/MM/YYYY) | | | | | | | | |

Date biopsy sent to central laboratory (DD/MM/YYYY) | | | | | | | | |

☐ N/A
(tick if:
- <8 cycles given
- Patient is PET negative after 8 cycles
- Patient has not consented for repeat biopsy)

Blood sample for translational research *(to be taken 1 month after treatment)*

Date sample taken (DD/MM/YYYY) | | | | | | | | |

Date sample sent to central laboratory (DD/MM/YYYY) | | | | | | | | |

☐ N/A
(tick if not applicable at this visit)

☐ Sample not taken

Please give reason for not taking sample:

Completed by:

Signature:

CRFs should only be completed by appropriately qualified personnel detailed on the site delegation log

Date completed: D D M M Y Y Y Y

Please return to: **ANIMATE** Trial Coordinator, CR UK & UCL Cancer Trials Centre, 90 Tottenham Court Road, London, W1T 4TJ

For UCL CTC use only: Date Checked: _____ Initials: _____ Date entered: _____ Initials: _____

Additional instructions for completing forms

Follow Up Form (for patients who received nivolumab)

The Follow Up Form is used for all patients who received nivolumab treatment, this form should be used after the decision has been made to stop treatment.

Completing the form

- This form should be completed at the end of months 1, 2, 3, 6, 9 and 12 in the first year after stopping trial treatment. The Annual Follow Up form should then be used.
- The form should be submitted to UCL CTC within 4 weeks of the patient being seen

Specific Fields

- Not all investigations are due at each visit. Each question outlines when that investigation is required. If it does not need answering at this visit then please tick the N/A box to the right of the question.
- A quick reference guide to patients outlining what is required at each visit is included in the trial protocol as appendix 2, please consult for further clarification.
- For late toxicity assessment, please see CTCAE v5 for guidance on event terms and grading.
- Please see section 12.2.2 of the protocol to see if the event meets the criteria for an AESI/SAE and submission of an SAE report form.

If you have any questions about how to complete this form please contact the ANIMATE Trial Coordinator on:
020 7679 9860

ANIMATE

Trial Number A N M – ☐☐☐ Patient Initials ☐☐☐

Annual Follow Up Form (1/1) (for patients who received nivolumab) Year ☐

Disease status

Date of assessment (DD/MM/YYYY) ☐☐☐☐☐☐☐☐

Has the patient died? ☐ Yes ☐ No
If yes, please complete a death form

Has the patient relapsed or progressed? ☐ Yes ☐ No

Has the patient started a new treatment for Hodgkin lymphoma? ☐ Yes ☐ No
If this is the patient's first treatment post–Nivolumab, please complete a new treatment form

Assessment for late toxicity of nivolumab

Date of assessment (DD/MM/YYYY) ☐☐☐☐☐☐☐☐

Has the patient experienced any late toxicity attributed to nivolumab? ☐ Yes ☐ No

If yes, please specify below, including any treatment:

Please continue to report AESI/SAEs later than 5 months post trial treatment if the event is considered to be a late effect of nivolumab (see protocol section 12.2.2 for guidance)

FOR UCL CTC USE ONLY:

SAE number: _____

Completed by:

CRFs should only be completed by appropriately qualified personnel detailed on the site delegation log

Signature:

Date completed: D D M M Y Y Y Y

For UCL CTC use only: Date Checked: _____ Initials: _____ Date entered: _____ Initials: _____

Additional instructions for completing forms

Annual Follow Up Form

The Annual Follow Up Form is used for all patients who received nivolumab treatment from the 2 year post-treatment visit onwards

Completing the form

- This form should be completed annually, starting at 2 years after post-treatment and then submitted annually thereafter until the end of trial is declared.
- The form should be submitted within 4 weeks of the patient being seen.
- Please continue to report AESI/SAEs later than 5 months post trial treatment if the event is considered to be a late effect of nivolumab (see protocol section 12.2.2 for guidance).

Specific Fields

- **Year** should reflect the number of years post-treatment, e.g. for the 2 years post-treatment follow up visit, please enter “2”.
- A quick reference guide to patients outlining what is required at each visit is included in the trial protocol as appendix 2, please consult for further clarification.

If you have any questions about how to complete this form please contact the ANIMATE Trial Coordinator on:
020 7679 9860

ANIMATE

Trial Number A N M – | | |

Patient Initials | | |

Follow Up Form (1/1) (for patients who did not receive nivolumab)

Month | |

Year | |

Disease status *(at follow up months 3, 6, 9 and 12 post PET0, and annually thereafter)*

Date of assessment (DD/MM/YYYY) | | | | | | | | |

Has the patient died?
If yes, please complete a death form
☐ Yes ☐ No

Has the patient relapsed or progressed?
If yes, please complete a disease progression form
☐ Yes ☐ No

Completed by:

Signature:

CRFs should only be completed by appropriately qualified personnel detailed on the site delegation log

Date completed: D D M M Y Y Y Y

Please return to: ANIMATE Trial Coordinator, CR UK & UCL Cancer Trials Centre, 90 Tottenham Court Road, London, W1T 4TJ

For UCL CTC use only: Date Checked: _____ Initials: _____ Date entered: _____ Initials: _____

Additional instructions for completing forms

Follow Up Form (for patients who did not receive nivolumab)

This Follow Up Form is used for all patients who did not receive nivolumab treatment, after being confirmed as PET negative at trial entry.

Completing the form

- This form should be completed at months 3, 6, 9 and 12 post-PET0, and annually thereafter until the end of trial is declared.
- The form should be submitted to UCL CTC within 4 weeks of the patient being seen.

Specific Fields

- **Year** should reflect the number of years post PET0, e.g. for the patient's follow up visit 2 years after PET0, please enter "2".
- A quick reference guide to patients outlining what is required at each visit is included in the trial protocol as appendix 2, please consult for further clarification.

If you have any questions about how to complete this form please contact the ANIMATE Trial Coordinator on:
020 7679 9860

ANIMATE

Trial Number A N M – ☐☐☐ Patient Initials ☐☐☐

Transplant Form (1/1)

Transplant

Date of transplant (DD/MM/YYYY) ☐☐☐☐☐☐☐☐

Type of transplant ☐ Autologous ☐ Allogeneic

For allogeneic transplants only

Donor source ☐ Sibling ☐ Matched unrelated donor (8/8) ☐ Mismatched unrelated donor (7/8) ☐ Haploidentical ☐ Cord blood

Graft source ☐ Peripheral blood stem cells ☐ Bone marrow ☐ Cord blood

Conditioning ☐ Myeloablative ☐ Reduced intensity

T-cell depletion? ☐ Yes ☐ No

Please specify GvHD prophylaxis

☐ Ciclosporin ☐ Tacrolimus OR ☐ Other Please specify:

Completed by:

Signature:

CRFs should only be completed by appropriately qualified personnel detailed on the site delegation log

Date completed: D D M M Y Y Y Y

For UCL CTC use only: Date Checked: _____ Initials: _____ Date entered: _____ Initials: _____

Additional instructions for completing forms

Transplant Form

The Transplant Form is used to record all transplants given post trial treatment.

Completing the form

- The form should be submitted as necessary with the next due follow up form.

Specific Fields

- *Transplant*
  - *Please give the date, type of transplant and cell dose given at transplant*

- *For allogeneic transplant only*
  - *Please only complete this section if the type of transplant question in the Transplant section above was answered as being allogeneic*
  - *Please give the donor source, graft source and the conditioning regimen used for the transplant*
  - *Please confirm if the patient underwent T-cell depletion and what GvHD prophylaxis was given to the patient*

If you have any questions about how to complete this form please contact the ANIMATE Trial Coordinator on:
020 7679 9860

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

POST-ALLOGENEIC TRANSPLANT URGENT EVENT FORM FAX

Number of pages (including cover):
Date:
Name of sender:
Site Name:
Contact telephone number:
Contact email address:

Report due within 72 hours of becoming aware of event

Please fax to **020 7679 9861** or email to **ctc.animate@ucl.ac.uk**

General enquires: 020 7679 9860
E-mail: ctc.animate@ucl.ac.uk

FOR UCL CTC USE ONLY:

Incident report number: _____

ANIMATE

Trial Number A N M – | | |

Patient Initials | | |

Post-Allogeneic Transplant Form (1/2)

Urgent Event

Post-Allogeneic Transplant Event

Please see section 12.5.1 of the trial protocol for full details regarding post-allogeneic transplant events.

Date of transplant (DD/MM/YYYY) | | | | | | | | |

Date of event onset (DD/MM/YYYY) | | | | | | | | |

Date site became aware of event onset (DD/MM/YYYY) | | | | | | | | |

Date of assessment (DD/MM/YYYY) | | | | | | | | |

Did the patient experience Acute GvHD? Occurring from days 0 to 100 after date of transplant. N.B. Only grades 3-4 acute GvHD counts as an urgent event as per protocol section 12.5.1

☐ Yes ☐ No

Did the patient experience Hyperacute GvHD? occurring up to 14 days after date of transplant

☐ Yes ☐ No

Maximum overall aGvHD grade ☐ Grades 3-4 Please appendix 4 in protocol for guidance

Maximum skin grade ☐ Maximum liver grade ☐ Maximum gut grade ☐

GvHD assessment confirmed by treating clinician listed on delegation log (name): _____

For UCL CTC use only: Date Checked: _____ Initials: _____ Date entered: _____ Initials: _____

ANIMATE

Trial Number A N M – ☐☐☐ Patient Initials ☐☐☐

Post-Allogeneic Transplant Form (2/2)

Urgent Event

Has the patient experienced any off the following:

Sinusoidal obstruction ☐ Yes ☐ No

If yes, please confirm which two of the following criteria occurred within 20 days after stem cell infusion:

Bilirubin >17.1 µmol/L ☐ Hepatomegaly and/or tenderness or pain over the liver ☐ Weight gain >20% above baseline ☐

Any other non-infectious febrile episodes requiring steroid therapy (including steroid-responsive febrile syndrome)? ☐ Yes ☐ No

If yes, please confirm which of the following features the patient experienced:

Major Criteria for steroid-responsive febrile syndrome

Non-infectious fever ☐ Rash covering >25% of body surface area ☐ Non-cardiac pulmonary oedema ☐

Minor Criteria for steroid-responsive febrile syndrome

Bilirubin >17.1 µmol/L ☐ AST >2 x upper limit of normal ☐ Weight gain >2.5% above baseline ☐

Creatinine >2 x baseline ☐

Any other post-transplant immune complications?
If yes, please specify:

☐ Yes ☐ No

Completed by:

Signature:

CRFs should only be completed by appropriately qualified personnel detailed on the site delegation log

Date completed: D D M M Y Y Y Y

For UCL CTC use only: Date Checked: _____ Initials: _____ Date entered: _____ Initials: _____

Additional instructions for completing forms

Post-Allogeneic Transplant Form

The Post-Allogeneic Transplant Form should be completed if a patient experiences any Post-allogeneic transplant events.

Completing the form

- This form should be submitted **within 72 hours of becoming aware of the event. This is an urgent event for this trial.**

Specific Fields

- ***Please see section 12.5.1 of the trial protocol for full details regarding post-allogeneic transplant events.***

If you have any questions about how to complete this form please contact the ANIMATE Trial Coordinator on:
020 7679 9860

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

DISEASE PROGRESSION URGENT EVENT FORM FAX

Number of pages (including cover):
Date:
Name of sender:
Site Name:
Contact telephone number:
Contact email address:

Report due within 72 hours of becoming aware of event

Please fax to **020 7679 9861** or email to **ctc.animate@ucl.ac.uk**

General enquires: 020 7679 9860
E-mail: ctc.animate@ucl.ac.uk

FOR UCL CTC USE ONLY:

SAE number: _____

Incident report number: _____

ANIMATE

Trial Number A N M – | | |

Patient Initials | | |

Disease Progression Form

Urgent Event

Progression / Relapse

Date of confirmed progression / relapse (DD/MM/YYYY) | | | | | | | | |

Please complete the annual follow up form from now on even if the patient is less than 12 months post-treatment

Date site became aware of progression / relapse (DD/MM/YYYY) | | | | | | | | |

Did the relapse occur at the site of prior disease (i.e. involved before initial salvage therapy)? ☐ Yes ☐ No

Was the relapse causally related to nivolumab? ☐ Yes *Please also submit an SAE form* ☐ No

Signature of clinician that assessed causality

If the patient has received treatment for relapsed disease, please complete a New Treatment Form

Biopsy

Was a biopsy taken? ☐ Yes ☐ No

Date sample taken (DD/MM/YYYY) | | | | | | | | |

Date sample sent for central review (DD/MM/YYYY) | | | | | | | | |

If biopsy not taken or sent for central review, please give reason:

Completed by:

Signature:

CRFs should only be completed by appropriately qualified personnel detailed on the site delegation log

Date completed: D D M M Y Y Y Y | | | | | | | | |

Please return to: ANIMATE Trial Coordinator, CR UK & UCL Cancer Trials Centre, 90 Tottenham Court Road, London, W1T 4TJ

For UCL CTC use only: Date Checked: _____ Initials: _____ Date entered: _____ Initials: _____

Additional instructions for completing forms

Disease Progression Form

The Disease Progression Form should be completed when the cancer relapses/ progresses.

Completing the form

- This form should be submitted when a patient relapses or has disease progression **within 72 hours of becoming aware of the event. This is an urgent event for this trial.**

- Patients diagnosed with disease progression should be followed up annually thereafter, even if they are less than 12 months post-treatment.

Specific Fields

- **Causal relationship with nivolumab**: This must be assessed by a clinician delegated the duty of assessing AE/SAE causality on the delegation log. If there is a reasonable possibility that nivolumab caused disease progression, an SAE report must be submitted to UCL CTC.
- A **biopsy** is to be performed at relapse if clinically indicated and the block is to be sent to HMDS for further analysis.

If you have any questions about how to complete this form please contact the ANIMATE Trial Coordinator on:
020 7679 9860

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

DEATH URGENT EVENT FORM
FAX

Number of pages (including cover):
Date:
Name of sender:
Site Name:
Contact telephone number:
Contact email address:

Report due within 24 hours of becoming aware of death

Please fax to **020 7679 9861** or email to **ctc.animate@ucl.ac.uk**

General enquires: 020 7679 9860
E-mail: ctc.animate@ucl.ac.uk

FOR UCL CTC USE ONLY:

SAE number: _____

Incident report number: _____

CANCER RESEARCH UK

Cancer Research UK and UCL Cancer Trials Centre

UCL

ANIMATE

Trial Number A N M – ☐☐☐ Patient Initials ☐☐☐

Death Form (1/2)

Urgent Event

Death

Date of Death (DD/MM/YYYY) ☐☐☐☐☐☐☐☐

Date site became aware of patient's death (DD/MM/YYYY) ☐☐☐☐☐☐☐☐

Cause of Death

- ☐ Hodgkin Lymphoma
- ☐ Nivolumab related*
- ☐ Combination of Hodgkin Lymphoma and Nivolumab related*
- ☐ Other treatment for Hodgkin Lymphoma:
  - ☐ Chemotherapy
  - ☐ Transplant related: Allogeneic
  - ☐ Transplant related: Autologous
  - ☐ Other *please specify:*
- ☐ Second Primary Malignancy *please specify:*
- ☐ Other *please specify:*

Please see trial protocol section 12.2.2 for details of events requiring SAE reporting and submit an SAE report form if reporting requirements met.

Death is an urgent event for this trial, please report within 24 hours of becoming aware of the death.

For UCL CTC use only: Date Checked: _____ Initials: _____ Date entered: _____ Initials: _____

ANIMATE

Trial Number A N M – ☐☐☐ Patient Initials ☐☐☐

Death Form (2/2)

Urgent Event

Death Certificate

Has the death certificate been reviewed? ☐ Yes ☐ No

If yes, please list cause of death recorded on Death Certificate:

1a

1b

1c

2

Post Mortem

Post Mortem Performed? ☐ Yes ☐ No

If yes, is the Post Mortem Report Enclosed? ☐ Yes ☐ No

Completed by:

Signature:

CRFs should only be completed by appropriately qualified personnel detailed on the site delegation log

Date completed: D D M M Y Y Y Y

Please return to: ANIMATE Trial Coordinator, CR UK & UCL Cancer Trials Centre, 90 Tottenham Court Road, London, W1T 4TJ

For UCL CTC use only: Date Checked: _____ Initials: _____ Date entered: _____ Initials: _____

Additional instructions for completing forms

The Death form should be completed where the patient has died

Death is an urgent event for this trial, please complete and fax/email this form to UCL CTC within 24 hours of becoming aware of the death.

Completing the form

- The form should be completed at any point from registration onto the trial
- Ensure that, if required, an SAE form is sent with the death form
- Ensure that all treatment and follow-up forms due up to the date of death have been submitted—any outstanding forms should be submitted as soon as possible

If you have any questions about how to complete this form please contact the ANIMATE Trial Coordinator on:
020 7679 9860

ANIMATE

Trial Number A N M – | | |

Patient Initials | | |

Lost to Follow Up Form

Please specify patient's status:

☐ **Lost to Follow Up** *Please complete Sections A & C*

☐ **Withdrawn consent** *Please complete Sections B & C*

A: Lost to Follow Up

Date the patient was last known to be alive (DD/MM/YYYY) | | | | | | | | |

Reason patient was lost to follow up

☐ Moved Away ☐ Emigrated ☐ Lost Contact

☐ Other (specify reason)

B: Withdrawn Consent

Date patient withdrew consent (DD/MM/YYYY) | | | | | | | | |

Please specify for which aspects of the trial the patient has withdrawn consent (*even though they cannot be personally identified in any results or publications i.e. anonymity will be preserved*):

1. Trial Follow Up
Patient has withdrawn from all future follow up visits and investigations mandated by the trial protocol. Outcome data will continue to be collected unless indicated below. ☐ Yes ☐ No

2. Future Data Collection: Hospital Notes/GP
Patient has withdrawn consent for collection of any further data from hospital notes or their GP. ☐ Yes ☐ No

3. Future Data Collection: NHS / Trial Registries
Patient has withdrawn consent for collection of information about their future health status from NHS Digital/ national health registries. ☐ Yes ☐ No

4. Biological Samples
Patient has withdrawn consent for any previously collected tissue/blood samples to be used in future research ☐ Yes ☐ No

C: Contact Details

If available, please provide contact details of patient's GP or referral hospital to assist with collection of data regarding patient's future health status (*only if patient has consented, and has not withdrawn such consent*)

Contact Name:

Contact's Role (GP, Nurse etc):

Contact Address:

Completed by:

Signature:

CRFs should only be completed by appropriately qualified personnel detailed on the site delegation log

Date completed: D D M M Y Y Y Y | | | | | | | | |

For UCL CTC use only: Date Checked: _____ Initials: _____ Date entered: _____ Initials: _____

Additional instructions for completing forms

Lost to Follow Up Form

The Lost to Follow Up Form should be completed when:

- A patient is in the follow up stage of treatment and it is not possible to record the follow up information.
- A patient has withdrawn consent to one or more of the activites listed in section B.

The form should not be completed if a patient is withdrawn from trial treatment, but remains in follow up for the trial.

Completing the form

- This form should be submitted as necessary within one month of the patient being lost to follow up.
- If the patient is lost to Follow Up complete section A and C
- If the patient has withdrawn consent complete sections B and C

Specific Fields

- *Section B*
  - *Date patient withdrew consent*– If the patient has withdrawn consent enter the date consent has been withdrawn
  - *1. Trial Follow Up*– If the patient withdraws from all future scans and visits tick Yes
  - *2. Future Data Collection: Hospital Notes/ GP*– If the patient withdraws consent for further data collection from notes or from their GP tick Yes
  - *3. Future Data Collection: NHS Information Service*– If the patient withdraws consent for collection of information about their future health tick Yes

If you have any questions about how to complete this form please contact the ANIMATE Trial Coordinator on:
020 7679 9860

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

TRANSFER OF CARE FAX

Number of pages (including cover):
Date:
Name of sender:
Site Name:
Contact telephone number:
Contact email address:

This form should only be used when the patient is moving from one trial site to another at any point during the trial

Please fax to **020 7679 9861** or email to **ctc.animate@ucl.ac.uk**

General enquires: 020 7679 9860
E-mail: ctc.animate@ucl.ac.uk

ANIMATE

Trial Number A N M – | | | |

Patient Initials | | |

Transfer of Care Form (1/1)

A transfer of care form must be completed each time a patient's care is transferred **from one trial site to another** at any point during the trial.

Please note that a patient's care transfers to a hospital that is not taking part in the ANIMATE trial, this form should **not** be submitted. Their original trial site or the last trial site where the patient was seen for the trial will remain responsible for providing data.

Name of current site:

ANIMATE treatment pathway completed under care of current centre (tick all that apply):

- ☐ Trial registration
- ☐ Post-registration investigations / confirmation of treatment eligibility
- ☐ Trial treatment
- ☐ PET-CT Scans
- ☐ Follow Up
- ☐ Further treatment
- ☐ Transplant

Date last seen at current site (DD/MM/YYYY)

Please submit all data up to the date of transfer to UCL CTC promptly and send a copy to the new site

Transferring to (name of hospital)

Consultant name

Completed by:

CRFs should only be completed by appropriately qualified personnel detailed on the site delegation log

Signature:

Date completed: D D M M Y Y Y Y

For UCL CTC use only: Date Checked: _____ Initials: _____ Date entered: _____ Initials: _____

Additional instructions for completing forms

Transfer of Care Form

Completing the form

- This form should be submitted when a patient's care is transferred from one trial site to another at any point during the trial within two weeks of the transfer of care to another site.
- If the patient is transferring to a hospital that is not open for the trial, the responsibility for data will remain with the last trial site where the patient was seen, and this form should not be used.
- UCL CTC can be contacted for a current list of active sites (email ctc.animate@ucl.ac.uk or call 0207 679 9860).
- Copies of the patient CRFs up to the date of transfer should be provided to the new trial site taking on their care.

If you have any questions about how to complete this form please contact the ANIMATE Trial Coordinator on:
020 7679 9860

ANIMATE

Trial Number A N M – ☐☐☐ Patient Initials ☐☐☐

New Treatment Form (1/2)

Is this is an initial report or an update? ☐ Initial ☐ Update

This form should be sent with the next due Follow Up Form.

Systemic treatment for lymphoma

Did the patient receive systemic treatment? ☐ Yes ☐ No

Start date of new treatment (DD/MM/YYYY) ☐☐☐☐☐☐☐☐

End date of new treatment (DD/MM/YYYY) ☐☐☐☐☐☐☐☐

What kind of regimen did the patient receive?

Chemotherapy ☐

Chemotherapy + monoclonal antibody ☐

Monoclonal antibody therapy alone ☐

Other *(Please specify)* ☐

Please specify the regimen given:

Number of cycles given ☐

If excessive toxicity is observed that is considered to be potentially due to nivolumab treatment, please submit an SAE form.

Radiotherapy

Did the patient receive radiotherapy? ☐ Yes ☐ No

Start date of new treatment (DD/MM/YYYY) ☐☐☐☐☐☐☐☐

End date of new treatment (DD/MM/YYYY) ☐☐☐☐☐☐☐☐

Please specify site(s) irradiated:

Radiotherapy dose: _____ Gy _____ Fractions

For UCL CTC use only: Date Checked: _____ Initials: _____ Date entered: _____ Initials: _____

ANIMATE

Trial Number A N M – ☐☐☐ Patient Initials ☐☐☐

New Treatment Form (2/2)

Transplant

Did the patient receive a transplant? ☐ Yes ☐ No

If yes, please complete and submit the Transplant form.

Response to new treatment

Date of response assessment (DD/MM/YYYY)
Please specify below: ☐☐☐☐☐☐☐☐ OR Not due yet ☐

PET-CT

☐ Complete Metabolic Response (CMR)
☐ Partial Metabolic Response (PMR)
☐ No Metabolic Response (NMR)
☐ Progressive Metabolic Disease (PMD)

Please see appendix 3 of the trial protocol for guidance

CT

☐ Complete Response (CR)
☐ Partial Response (PR)
☐ Stable Disease (SD)
☐ Progressive Disease (PD)

Completed by:

Signature:

CRFs should only be completed by appropriately qualified personnel detailed on the site delegation log

Date completed: D D M M Y Y Y Y

For UCL CTC use only: Date Checked: _____ Initials: _____ Date entered: _____ Initials: _____

Additional instructions for completing forms

New Treatment Form

The New Treatment Form should be completed if a patient receives any further treatment for Hodgkin Lymphoma post-trial treatment.

Completing the form

- The form should be submitted as necessary with the next due follow up form.
- If the patient has received further treatment for their Hodgkin Lymphoma then please complete this form as appropriate.

Specific Fields

- **Systemic treatment for Lymphoma** — Please answer *yes* or *no* for 'did the patient receive systemic treatment?'. If answered yes, please complete this section stating the start and end date of treatment, what regimen and how many cycles were given. If excessive toxicity is observed that is considered to be potentially due to nivolumab treatment, please submit an SAE form.

- **Radiotherapy** — Please answer *yes* or *no* for 'did the patient receive radiotherapy?' If answered yes, please complete this section stating the start and end date of treatment, what sites were irradiated and the dose given.

- **Transplant** — Please answer *yes* or *no* for 'did the patient receive a transplant?' If answered yes, please complete and submit the Transplant form.

- **Response to new treatment**—Please give the response to new treatment and the date of this assessment, or tick the box for *not yet due* if treatment is still ongoing. An update report should then be sent with a subsequent follow up form.

  Please see appendix 3 of the trial protocol for further guidance on PET-CT based response assessment.

If you have any questions about how to complete this form please contact the ANIMATE Trial Coordinator on:
020 7679 9860

Cancer Research UK & UCL Cancer Trials Centre **ANIMATE** **ROLLING ADVERSE EVENT FORM COVER PAGE**

Trial No: ANM - ☐☐☐ **Initials:** ☐☐☐ **Site:** _____

Please complete each column and return this cover page along with the treatment/follow up at each trial timepoint listed below.
Please submit the AE form with the cover page ONLY when there are new AEs or changes to existing AEs.

Trial Timepoint (or date)	PRINT NAME of delegated person:	SIGNATURE of delegated person:	Date *(dd mm yyyy)*	If no AEs or no change to AE form since last assessment, please tick:
Nivolumab Treatment				
Cycle 1	CRF completion by:		☐☐☐☐☐☐☐☐	☐
	Causality by:		☐☐☐☐☐☐☐☐	Please re-assess causality if box above is NOT ticked
Cycle 2	CRF completion by:		☐☐☐☐☐☐☐☐	☐
	Causality by:		☐☐☐☐☐☐☐☐	Please re-assess causality if box above is NOT ticked
Cycle 3	CRF completion by:		☐☐☐☐☐☐☐☐	☐
	Causality by:		☐☐☐☐☐☐☐☐	Please re-assess causality if box above is NOT ticked
Cycle 4	CRF completion by:		☐☐☐☐☐☐☐☐	☐
	Causality by:		☐☐☐☐☐☐☐☐	Please re-assess causality if box above is NOT ticked
Cycle 5	CRF completion by:		☐☐☐☐☐☐☐☐	☐
	Causality by:		☐☐☐☐☐☐☐☐	Please re-assess causality if box above is NOT ticked
Cycle 6	CRF completion by:		☐☐☐☐☐☐☐☐	☐
	Causality by:		☐☐☐☐☐☐☐☐	Please re-assess causality if box above is NOT ticked
Cycle 7	CRF completion by:		☐☐☐☐☐☐☐☐	☐
	Causality by:		☐☐☐☐☐☐☐☐	Please re-assess causality if box above is NOT ticked
Cycle 8	CRF completion by:		☐☐☐☐☐☐☐☐	☐
	Causality by:		☐☐☐☐☐☐☐☐	Please re-assess causality if box above is NOT ticked

Follow Up				
1 month	**CRF completion by:**		☐☐☐☐☐☐☐☐	☐
	Causality by:		☐☐☐☐☐☐☐☐	**Please re-assess causality if box above is NOT ticked**
2 months *Mark as N/A if patient has started new lymphoma treatment prior to 1 month follow up visit*	**CRF completion by:**		☐☐☐☐☐☐☐☐	☐
	Causality by:		☐☐☐☐☐☐☐☐	**Please re-assess causality if box above is NOT ticked**
3 months *Mark as N/A if patient has started new lymphoma treatment prior to 2 months follow up visit*	**CRF completion by:**		☐☐☐☐☐☐☐☐	☐
	Causality by:		☐☐☐☐☐☐☐☐	**Please re-assess causality if box above is NOT ticked**
Additional AE Form Updates e.g. if an amendment is made following a query on a DCR report or a monitoring action from the CTC				
	CRF completion by:		☐☐☐☐☐☐☐☐	☐
	Causality by:		☐☐☐☐☐☐☐☐	**Please re-assess causality if box above is NOT ticked**
	CRF completion by:		☐☐☐☐☐☐☐☐	☐
	Causality by:		☐☐☐☐☐☐☐☐	**Please re-assess causality if box above is NOT ticked**
	CRF completion by:		☐☐☐☐☐☐☐☐	☐
	Causality by:		☐☐☐☐☐☐☐☐	**Please re-assess causality if box above is NOT ticked**
	CRF completion by:		☐☐☐☐☐☐☐☐	☐
	Causality by:		☐☐☐☐☐☐☐☐	**Please re-assess causality if box above is NOT ticked**
	CRF completion by:		☐☐☐☐☐☐☐☐	☐
	Causality by:		☐☐☐☐☐☐☐☐	**Please re-assess causality if box above is NOT ticked**

Cancer Research UK & UCL Cancer Trials Centre **ANIMATE** **ROLLING ADVERSE EVENT FORM**

Trial No: ANM -		Initials:		Site:		Page _____ of _____

Adverse Event *(If possible, use term as listed in CTCAE v5.0)*	Worst Severity Grade[1] *(Grades 1-5) For pre-printed AEs: If no AE experienced code as 0 and do not complete the columns to the right*	Seriousness Criteria[2] *(Enter all that apply)*	SAE Report Submitted *0 = No* *1 = Yes[3]*	AE of Special Interest?[4]	Date of Onset *d d m m y y y y* *(e.g. 28 – 01 – 2011)*	Outcome[5]	Causal relationship with Nivolumab[6]
Colitis							
Diarrhoea							
Pneumonitis							
Alanine aminotransferase increased							
Aspartate aminotransferase increased							
Blood bilirubin increased							
Rash maculopapular							
Erythroderma							

1) Use CTCAE v5.0 where possible
2) Enter code: 0 = not serious; 1 = Required new or prolonged hospitalisation; 2 = Resulted in persistent or significant disability/incapacity; 3 = Resulted in congenital anomaly or birth defect; 4 = Life threatening; 5 = Resulted in death; 6 = other medically significant
3) If seriousness criteria is 1 to 6, ensure a completed SAE Report has been submitted to the UCL CTC, unless stated in protocol as exempt
4) Enter code: 0 = No; 1 = Yes/AESI; Refer to protocol for events qualifying as AEs of Special Interest for this trial. If applicable, please, submit a completed SAE Report to UCL CTC
5) Enter code: 1 = Not resolved; 2 = Resolved; 3 = Resolved with sequelae; 4 = Resolving; 5 = Fatal. Note: If the outcome is Unknown, please enter as Not Resolved, until a resolution is known.
6) Enter code: 0 = Not related (no reasonable possibility) 1 = Related (reasonable possibility)

Please return to: ANIMATE Trial Co-ordinator, CR UK & UCL Cancer Trials Centre, 90 Tottenham Court Road, London, W1T 4TJ, United Kingdom

For CTC use only: Date form received: _____ Date form checked: _____ Date form entered: _____ Initials: _____

For CTC use only: Date form received: _____ Date form checked: _____ Date form entered: _____ Initials: _____

Cancer Research UK & UCL Cancer Trials Centre — ANIMATE — ROLLING ADVERSE EVENT FORM

Trial No: ANM - ☐☐☐	**Initials:** ☐☐☐	**Site:** _____	**Page** _____ **of** _____

Adverse Event *(If possible, use term as listed in CTCAE v5.0)*	**Worst Severity Grade[1]** *(Grades 1-5) For pre-printed AEs: If no AE experienced code as 0 and do not complete the columns to the right*	**Seriousness Criteria[2]** *(Enter all that apply)*	**SAE Report Submitted** *0 = No 1 = Yes[3]*	**AE of Special Interest[4]**	**Date of Onset** *d d m m y y y y (e.g. 28 – 01 – 2011)*	**Outcome[5]**	**Causal relationship with Nivolumab[6]**
Hyperthyroidism					☐☐☐☐☐☐☐☐		
Hypothyroidism					☐☐☐☐☐☐☐☐		
Adrenal insufficiency					☐☐☐☐☐☐☐☐		
Hyperglycaemia					☐☐☐☐☐☐☐☐		
Hypophysitis					☐☐☐☐☐☐☐☐		
Creatinine increased					☐☐☐☐☐☐☐☐		
Myocarditis					☐☐☐☐☐☐☐☐		
Uveitis					☐☐☐☐☐☐☐☐		

1) Use CTCAE v5.0 where possible
2) Enter code: 0 = not serious; 1 = Required new or prolonged hospitalisation; 2 = Resulted in persistent or significant disability/incapacity; 3 = Resulted in congenital anomaly or birth defect; 4 = Life threatening; 5 = Resulted in death; 6 = other medically significant
3) If seriousness criteria is 1 to 6, ensure a completed SAE Report has been submitted to the UCL CTC, unless stated in protocol as exempt
4) Enter code: 0 = No; 1 = Yes/AESI. Refer to protocol for events qualifying as AEs of Special Interest for this trial. If applicable, please, submit a completed SAE Report to UCL CTC
5) Enter code: 1 = Not resolved; 2 = Resolved; 3 = Resolved with sequelae; 4 = Resolving; 5 = Fatal. Note: If the outcome is Unknown, please enter as Not Resolved, until a resolution is known.
6) Enter code: 0 = Not related (no reasonable possibility) 1 = Related (reasonable possibility)

Please return to: ANIMATE Trial Co-ordinator, CR UK & UCL Cancer Trials Centre, 90 Tottenham Court Road, London, W1T 4TJ, United Kingdom

For CTC use only: Date form received: _____ Date form checked: _____ Date form entered: _____ Initials: _____

Cancer Research UK & UCL Cancer Trials Centre **ANIMATE** **ROLLING ADVERSE EVENT FORM**

Trial No: ANM -		Initials:		Site:		Page _____ of _____

Adverse Event *(If possible, use term as listed in CTCAE v5.0)*	Worst Severity Grade[1] *(Grades 1-5) For pre-printed AEs: If no AE experienced code as 0 and do not complete the columns to the right*	Seriousness Criteria[2] *(Enter all that apply)*	SAE Report Submitted *0 = No 1 = Yes[3]*	AE of Special Interest? [4]	Date of Onset *d d m m y y y y (e.g. 28 – 01 – 2011)*	Outcome[5]	Causal relationship with Nivolumab[6]
Infusion related reaction							

1) Use CTCAE v5.0 where possible
2) Enter code: 0 = not serious; 1 = Required new or prolonged hospitalisation; 2 = Resulted in persistent or significant disability/incapacity; 3 = Resulted in congenital anomaly or birth defect; 4 = Life threatening; 5 = Resulted in death; 6 = other medically significant
3) If seriousness criteria is 1 to 6, ensure a completed SAE Report has been submitted to the UCL CTC, unless stated in protocol as exempt
4) Enter code: 0 = No; 1 = Yes/AESI. Refer to protocol for events qualifying as AEs of Special Interest for this trial. If applicable, please, submit a completed SAE Report to UCL CTC
5) Enter code: 1 = Not resolved; 2 = Resolved; 3 = Resolved with sequelae; 4 = Resolving; 5 = Fatal. Note: If the outcome is Unknown, please enter as Not Resolved, until a resolution is known.
6) Enter code: 0 = Not related (no reasonable possibility) 1 = Related (reasonable possibility)

Please return to: ANIMATE Trial Co-ordinator, CR UK & UCL Cancer Trials Centre, 90 Tottenham Court Road, London, W1T 4TJ, United Kingdom

For CTC use only: Date form received: _____ Date form checked: _____ Date form entered: _____ Initials: _____

Cancer Research UK & UCL Cancer Trials Centre — ANIMATE — ROLLING ADVERSE EVENT FORM

Trial No: ANM -		Initials:		Site:		Page _____ of _____

Adverse Event *(If possible, use term as listed in CTCAE v5.0)*	Worst Severity Grade[1] *(Grades 1-5)* *For pre-printed AEs: If no AE experienced code as 0 and do not complete the columns to the right*	Seriousness Criteria[2] *(Enter all that apply)*	SAE Report Submitted *0 = No* *1 = Yes*[3]	AE of Special Interest[4]	Date of Onset *d d m m y y y y* *(e.g. 28 – 01 – 2011)*	Outcome[5]	Causal relationship with Nivolumab[6]

1) Use CTCAE v5.0 where possible
2) Enter code: 0 = not serious; 1 = Required new or prolonged hospitalisation; 2 = Resulted in persistent or significant disability/incapacity; 3 = Resulted in congenital anomaly or birth defect; 4 = Life threatening; 5 = Resulted in death; 6 = other medically significant
3) If seriousness criteria is 1 to 6, ensure a completed SAE Report has been submitted to the UCL CTC
4) Enter code: 0 = No; 1 = Yes/AESI. Refer to protocol for events qualifying as AEs of Special Interest for this trial. If applicable, please, submit a completed SAE Report to UCL CTC
5) Enter code: 1 = Not resolved; 2 = Resolved; 3 = Resolved with sequelae; 4 = Resolving; 5 = Fatal. Note: If the outcome is Unknown, please enter as Not Resolved, until a resolution is known.
6) Enter code: 0 = Not related (no reasonable possibility) 1 = Related (reasonable possibility)

Please return to: ANIMATE Trial Co-ordinator, CR UK & UCL Cancer Trials Centre, 90 Tottenham Court Road, London, W1T 4TJ, United Kingdom

For CTC use only: Date form received: _____ Date form checked: _____ Date form entered: _____ Initials: _____

Completion Instructions

- Research personnel completing the Adverse Event Form must be appropriately trained and authorised as per the trial delegation log. Record all adverse events (AEs) that occur from the start of nivolumab treatment until 3 months post last nivolumab administration or commencement of next treatment for lymphoma (whichever is earlier) whether related to the trial treatment or not.
- Pre-existing events (listed on the Post-Salvage Treatment Form) do not qualify as AEs unless they worsen or recur (i.e. resolve/improve and then worsen/reappear again).
- Complete the Rolling Adverse Event Form Cover Page at every trial timepoint listed on the form and if necessary, update the accompanying Adverse Event Form.

  Additional updates to the AE form may also be required e.g. in cases where a query on a DCR report or monitoring action leads to a change to the AE form. The Rolling Adverse Event Form Cover Page should also be completed at this time.

  Please submit a copy of the cover page to UCL CTC at each time point. The Rolling Adverse Event Form only needs to be sent when there are new AEs or changes to existing AEs (for example an increase in grade).

  Any updates or changes to previously reported AEs must be initialled and dated.

1) Severity Grade

- Enter AE worst grade – amend the form if the grade increases
- Use CTCAE v5.0 where possible

2) Seriousness Criteria

- Use the codes as listed on the Adverse Event Form. **For codes 1 to 6, if more than 1 code applies to the event, enter all codes that apply; however for code 0 (= non-serious), only this one code will apply.**

3) SAE Report Submitted

- If yes, ensure a completed SAE Report has been submitted to UCL CTC.

4) AEs of Special Interest

- Refer to the protocol (section 12.4) for a list of events which qualify as Adverse Events of Special Interest for this trial. Please note that an SAE report will also be required.

5) Date of Onset

- Refer to the date the event started. This is not the date when the event reached the maximum grade.

6) Outcome

- Please provide an outcome for each event using the codes listed on the Adverse Event Form.

7) Causality Assessment sign-off:

All adverse events reported on the Adverse Event Form must be reviewed and assessed by an Investigator.

- Documentation of Investigator review at each timepoint:

  The Rolling Adverse Event Form Cover Page should be submitted to UCL CTC at each of the timepoints listed, along with the relevant treatment/follow up case report form.

  The Investigator should sign and date the Rolling Adverse Event Form Cover Page to document review of the causality assessment at the first submission and at each subsequent timepoint where there are changes that could impact the causality assessment (e.g. addition of new AEs or changes to previously reported AEs). If the person completing the Adverse Event Form Cover Page ticks to confirm that there have been no new AEs or other changes to the Adverse Event Form since the previous assessment, the causality does not need to be re-assessed by the Investigator.

EudraCT number: 2017-002544-32	Bristol-Myers Squibb Trial Reference CA-209-445

FOR UCL CTC USE ONLY	SAE ID : ANM– ☐☐☐ — ☐☐ *(file SAE Report with SAE Sponsor Review Form)*

SERIOUS ADVERSE EVENT (SAE) REPORT

Please fax this form within 24 hours of becoming aware of the SAE to the ANIMATE Coordinator at the CR UK & UCL Cancer Trials Centre on +44 (0)20 7679 9861

Section 1 - Patient details

Patient Trial Number: ANM–☐☐☐ **Patient initials:** ☐☐☐ **Age at onset:** ☐☐☐ Years **Sex:** ☐ Male ☐ Female

Height: ☐☐☐ cm **Weight:** ☐☐☐.☐ kg **Site name:** _____ **Country: United Kingdom**

Section 2 - Initial report	Date site became aware of event (s) (DD/MM/YYYY)	Date reported to CTC (DD/MM/YYYY)	If reported to the CTC after 24 hours of becoming serious, please state reason in the box below (if applicable):

Section 3 - Follow up report (tick box if applicable) ☐	• *Initial & date all changes throughout the report.* • *Fax to the trials centre within 24 hours of becoming aware of significant new information.*

Section 4 - Serious Events (list serious events including AESIs below) – see page 2 of template for codes

Continued on a separate sheet? ☐ Y

Event No.	Event Term (refer to CTCAE v5.0)	Severity Grade (CTCAE v5.0)	Dates of event onset & resolution (dd/mm/yyyy)	Seriousness criteria[1]: *(enter all codes applicable for each event)*	Outcome of event[2]	Investigator's assessment of causal relation to event[3]: Nivolumab
01			*Onset* ☐☐ ☐☐ ☐☐☐☐ *Resolution* ☐☐ ☐☐ ☐☐☐☐			
02			*Onset* ☐☐ ☐☐ ☐☐☐☐ *Resolution* ☐☐ ☐☐ ☐☐☐☐			
03			*Onset* ☐☐ ☐☐ ☐☐☐☐ *Resolution* ☐☐ ☐☐ ☐☐☐☐			
04			*Onset* ☐☐ ☐☐ ☐☐☐☐ *Resolution* ☐☐ ☐☐ ☐☐☐☐			

Codes:

(1) Seriousness (enter all codes applicable to event): **1 = Required new or prolonged hospitalisation 2 = Resulted in persistent or significant disability/incapacity 3 = Resulted in congenital anomaly or birth defect 4 = Life threatening 5 = Resulted in Death 6 = Other medically significant - specify below (e.g. adverse event of special interest)**

(2) Outcome of Event (enter one code per event)**: 1 = Not Resolved 2 = Resolved 3 = Resolved with Sequelae 4 = Resolving 5 = Fatal**

(3) Causal Relationship (enter <u>one</u> code)**: 0 = "Not related (no reasonable possibility)" 1 = "Related (reasonable possibility)"**

If patient has died: **Date of death:** ☐☐ ☐☐ ☐☐☐☐ (d d m m y y y y) **Cause of death:** *(specify)* _____ **Autopsy report available?** *(this may be requested by UCL CTC if required)* Y ☐ N ☐

Dates of hospitalisation when seriousness criterion 1 is chosen: **Date of hospitalisation:** ☐☐ ☐☐ ☐☐☐☐ (d d m m y y y y) **Date of discharge:** ☐☐ ☐☐ ☐☐☐☐ (d d m m y y y y)

If an event(s) is medically significant, specify why:

Section 5 - IMPs **Most recent cycle number:** ☐

Active Substance	Brand Name	Batch Number	Formulation	Route	Protocol Dose	Frequency	Total Daily Dose Prior to Event Onset	Treatment error[1]	Date of First Administration of IMP AND Date of Final Administration of IMP (or tick "Ongoing" if treatment continued to date) AND Date of last IMP administration prior to event onset (dd/mm/yyyy)	Action Taken[2]	Complete if dose reduced/treatment stopped Y or N or N/A or UNK: Event(s) improved after stopping or reducing treatment?	Was the drug re-introduced?	If yes, did the event(s) reappear once reintroduced?
Nivolumab	**Opdivo®**		**Solution for infusion**	**IV**	**240mg**				*First* ☐☐ ☐☐ ☐☐☐☐ *Last* ☐☐ ☐☐ ☐☐☐☐ *Ongoing* ☐ *Date of last administration prior to SAE* ☐☐ ☐☐ ☐☐☐☐				

Codes:

(1) Enter one code: 0 = No issues 2 = Overdose 3 = Medication error 4 = Other: specify_____

(2) Action taken: 1 = Drug withdrawn permanently 2 = Drug withdrawn temporarily 3 = Dose not changed 4 = Unknown 5 = Not applicable (e.g. treatment not started prior to SAE onset, treatment completed prior to SAE onset)

Section 6 - Any relevant tests/laboratory data applicable to this SAE? Y ☐ N ☐ If yes, specify below *Continued on separate page?* ☐ Y

Date *(dd/mm/yyyy)*	**Test** *(specify)*	**Results** *(specify and include units, if applicable)*	**Results Pending** *(tick box if result has not been provided)*	**Normal range, if applicable** *(specify and include units, if applicable)*
☐☐ ☐☐ ☐☐☐☐			☐	
☐☐ ☐☐ ☐☐☐☐			☐	
☐☐ ☐☐ ☐☐☐☐			☐	
☐☐ ☐☐ ☐☐☐☐			☐	
☐☐ ☐☐ ☐☐☐☐			☐	

Section 7 – Any other non-serious events relevant to this case? Y ☐ N ☐ *If yes, list adverse event term below, with start and stop dates*

Section 8 - Any relevant medical history/concurrent conditions (both patient and family)? Y ☐ N ☐ *If yes, specify below with start and stop dates*

Section 9 - Treatment for SAE? Y ☐ N ☐ If yes, specify below. Please provide all relevant details available (indication, dose, frequency, start and stop dates)

Section 10 - Concomitant medications? Y ☐ N ☐ If yes, specify below *Only include drugs given within the 30 days prior to SAE onset excluding treatment for SAE. Use continuation page if necessary.* *Continued on separate page?* ☐ Y

Drug Name	Indication	Dose (include units)	Frequency	Route	Start date AND Stop Date or Ongoing (dd/mm/yyyy)
					Start ☐☐ ☐☐ ☐☐☐☐ *Stop* ☐☐ ☐☐ ☐☐☐☐ ☐ *Ongoing*
					Start ☐☐ ☐☐ ☐☐☐☐ *Stop* ☐☐ ☐☐ ☐☐☐☐ ☐ *Ongoing*
					Start ☐☐ ☐☐ ☐☐☐☐ *Stop* ☐☐ ☐☐ ☐☐☐☐ ☐ *Ongoing*
					Start ☐☐ ☐☐ ☐☐☐☐ *Stop* ☐☐ ☐☐ ☐☐☐☐ ☐ *Ongoing*
					Start ☐☐ ☐☐ ☐☐☐☐ *Stop* ☐☐ ☐☐ ☐☐☐☐ ☐ *Ongoing*

Section 11 - Were any SAEs listed on this form related to a concomitant medication? Y ☐ N ☐ *If yes, give details of adverse event term, drug name and if there was an interaction with the IMP*

Event Term (state Event Term as given in Serious Events section)	**Concomitant Medication** (list which concomitant medication is related to adverse event)	**Was the AE as a result of an interaction between the IMP and concomitant medication?**
		Y ☐ N ☐
		Y ☐ N ☐
		Y ☐ N ☐
		Y ☐ N ☐
		Y ☐ N ☐

Section 12 - Case Narrative

Continued on a separate sheet? ☐ Y

Section 13 - Investigator Assessment: *(must be authorised on staff delegation log to review SAEs and perform evaluations of causal relationship)*

Print Name: _____ **Signature:** _____ **Date of Assessment:** ☐☐ ☐☐ ☐☐☐☐ (d d m m y y y y)

Section 14 - Form(s) completed by: *(must be authorised on staff delegation log to complete CRFs and report SAEs)*

Print Name: _____ **Signature:** _____ **Date of Completion:** ☐☐ ☐☐ ☐☐☐☐ (d d m m y y y y)

Continuation pages

Section 4 - Serious events (continuation page)						
Event No.	**Event Term** (refer to CTCAE v5.0)	**Severity Grade** (CTCAE v5.0)	**Dates of event onset & resolution** (dd/mm/yyyy)	**Seriousness criteria[1]:** *(enter all codes applicable for each event)*	**Outcome of event[2]**	**Investigator's assessment of causal relation to event[3]:** **Nivolumab**
05			*Onset* ☐☐ ☐☐ ☐☐☐☐ *Resolution* ☐☐ ☐☐ ☐☐☐☐			
06			*Onset* ☐☐ ☐☐ ☐☐☐☐ *Resolution* ☐☐ ☐☐ ☐☐☐☐			
07			*Onset* ☐☐ ☐☐ ☐☐☐☐ *Resolution* ☐☐ ☐☐ ☐☐☐☐			
08			*Onset* ☐☐ ☐☐ ☐☐☐☐ *Resolution* ☐☐ ☐☐ ☐☐☐☐			
09			*Onset* ☐☐ ☐☐ ☐☐☐☐ *Resolution* ☐☐ ☐☐ ☐☐☐☐			
10			*Onset* ☐☐ ☐☐ ☐☐☐☐ *Resolution* ☐☐ ☐☐ ☐☐☐☐			

Codes:

(1) Seriousness (enter all codes applicable to event): **1 = Required new or prolonged hospitalisation 2 = Resulted in persistent or significant disability/incapacity 3 = Resulted in congenital anomaly or birth defect 4 = Life threatening 5 = Resulted in Death 6 = Other medically significant - specify below (e.g. adverse event of special interest)**

(2) Outcome of Event (enter one code per event)**: 1 = Not Resolved 2 = Resolved 3 = Resolved with Sequelae 4 = Resolving 5 = Fatal**

(3) Causal Relationship (enter one code)**: 0 = "Not related (no reasonable possibility)" 1 = "Related (reasonable possibility)"**

Section 6 - Tests/laboratory data (continuation page)

Date *(dd/mm/yyyy)*	Test *(specify)*	Results *(specify)*	Results Pending *(tick box if result has not been provided)*	Normal range, if applicable *(specify)*
☐☐ ☐☐ ☐☐☐☐			☐	
☐☐ ☐☐ ☐☐☐☐			☐	
☐☐ ☐☐ ☐☐☐☐			☐	
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☐☐ ☐☐ ☐☐☐☐			☐	

Section 9 - Concomitant medications (continuation page)

Drug Name	Indication	**Dose** (include units)	Frequency	Route	Start date AND Stop Date or Ongoing (dd/mm/yyyy)
					Start *Stop* *Ongoing*
					Start *Stop* *Ongoing*
					Start *Stop* *Ongoing*
					Start *Stop* *Ongoing*
					Start *Stop* *Ongoing*
					Start *Stop* *Ongoing*
					Start *Stop* *Ongoing*
					Start *Stop* *Ongoing*
					Start *Stop* *Ongoing*
					Start *Stop* *Ongoing*

Section 10 - Treatment for SAE (continuation page)

Treatment	Indication	**Dose** (include units)	Frequency	Route	**Start date AND Stop Date or Ongoing** (dd/mm/yyyy)
					Start *Stop* *Ongoing*
					Start *Stop* *Ongoing*
					Start *Stop* *Ongoing*
					Start *Stop* *Ongoing*
					Start *Stop* *Ongoing*
					Start *Stop* *Ongoing*
					Start *Stop* *Ongoing*
					Start *Stop* *Ongoing*
					Start *Stop* *Ongoing*
					Start *Stop* *Ongoing*

Section 12 - Case Narrative (continuation page)

ANIMATE

PREGNANCY REPORT

Please complete all sections with details of any pregnancy occurring from the first administration of nivolumab until 6 months after last trial treatment administration for trial patients **or** if the female partner of a male trial patient becomes pregnant between the start of trial treatment and 8 months after last trial treatment administration

Please fax this form to the ANIMATE Coordinator at the CR UK & UCL Cancer Trials Centre on 020 7679 9861 within 24 hours of notification of the event.

Trial details					
Trial title:	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				
Trial acronym:	ANIMATE	**EudraCT number:**	2017-002544-32	**Bristol- Myers Squibb Trial Reference:**	CA-209-445

Patient details *(Any information regarding female partners of trial patients should be entered in Other Pregnancy Information section)*			
Patient initials:	☐☐☐	**Patient trial number:**	**ANM -** ☐☐☐
Age at time of conception:	☐☐ Years	**Pregnancy report relates to:**	☐ Trial Patient ☐ Partner of Trial Patient
Hospital:		**Treating Clinician:**	
Type of report:	☐ **Initial** ☐☐ ☐☐ ☐☐☐☐ *d d m m y y y y*	☐ **Follow-up**	**For all follow-up reports, please:** • **initial & date all changes throughout the report.** • **fax to the trials centre within 24 hours of becoming aware of significant new information.**

Complete for initial reports only:	**Date site notified of pregnancy:** ☐☐ ☐☐ ☐☐☐☐ *d d m m y y y y*	**If reported to the CTC more than 24 hours after becoming aware of pregnancy, provide reason:** _____

ANIMATE

PREGNANCY REPORT

Patient trial number: ANM – ☐☐☐

IMP											Most recent cycle number: ☐
Name	**Manufacturer Name AND Brand Name**	**Batch Number**	**Strength (include units)**	**Total Daily Dose last given prior to Pregnancy confirmation** (include units)	**Frequency**	**Formulation**	**Route**	**Treatment Overdose[1]**	**Date of first administration of IMP** dd – mm – yyyy	**Date of last administration of IMP prior to pregnancy confirmation** dd – mm – yyyy	**Action Taken[2]**
Nivolumab	**Bristol-Myers Squibb - OPDIVO**		**10mg/ml**			**Concentrate for solution for infusion**	**IV**	☐	☐☐ ☐☐ ☐☐☐☐	☐☐ ☐☐ ☐☐☐☐	☐

Codes:
(1) Enter one code: 0 = no overdose 1 = dosing/administration error by site 3 = Other (specify) _____
(2) Action taken: 0 = Dose not changed 1 = Dose reduced 2 = Drug withdrawn/Treatment stopped
SEE PROTOCOL FOR ACTION THAT SHOULD BE TAKEN ON CONFIRMATION OF PREGNANCY (If action differs, give details in Other Pregnancy Information)

Pregnancy Information						
Start date of last menses	**Date pregnancy confirmed**	**Method of diagnosis**		**Anticipated date of childbirth**		**Mother consented for pregnancy monitoring?**
☐☐ ☐☐ ☐☐☐ d d m m m y y	☐☐ ☐☐ ☐☐☐ d d m m m y y			☐☐ ☐☐ ☐☐☐ d d m m m y y		☐ Y ☐ N ☐ Pending *
If consented for pregnancy monitoring:	☐ Trial patient, consented at study entry	If not consented at study entry (i.e. partners)	Date consent signed ☐☐ ☐☐ ☐☐☐ d d m m m y y	Pregnancy monitoring PIS version used:	☐.☐	Pregnancy monitoring consent form version used:	☐.☐
*** If mother has not yet consented for pregnancy monitoring:**	☐ Will be consented at next clinic visit	☐ Other (specify): _____					

ANIMATE

PREGNANCY REPORT

Patient trial number: ANM – ☐☐☐

Pregnancy Outcome – Complete the section *only if* the mother has given consent						*Please provide any further information in Other Pregnancy Information section below*
☐ Not known at this date	☐ Live birth/ healthy baby	☐ Induced abortion[1]	☐ Spontaneous abortion[1]	☐ Still birth[1]	☐ Neonatal death[1]	Date of Pregnancy outcome: ☐☐ ☐☐ ☐☐☐☐ dd – mm - yyyy
Was there any evidence of congenital abnormalities?	☐ Yes[1]	☐ No	☐ Not known			

(1) For adverse pregnancy outcomes please provide further information in the narrative and ensure a clinician assesses causality	Adverse outcome causally related to IMP? ☐ Y* ☐ N	Adverse outcome causally related to Concomitant Medication? ☐ Y ☐ N	*SAE report submitted? ☐ Y* ☐ N	*SAE report must be submitted within 24 hours of becoming aware of adverse outcome*

* *Please complete and submit an SAE form for all adverse outcomes deemed to be causally related to trial treatment. IMP sections do not need to be duplicated on the SAE Report if provided on the Pregnancy Report.*

Date of delivery dd – mm – yyyy	**Gestation (weeks)**	**Mode of Delivery**	**Sex**	**Weight (kg)**	**Antenatal Problems**	**Postnatal Problems**
☐☐ ☐☐ ☐☐☐☐	☐☐		☐ Male ☐ Female	☐.☐		

If multiple birth, please provide the above details for each additional baby under 'Other Pregnancy Information' below

Other Pregnancy Information– Complete the section *only if* the mother has given consent
(e.g. action taken, concurrent conditions, medical history, complications during birth, birth defects, causality details etc.)

ANIMATE

PREGNANCY REPORT

Patient trial number: ANM – ☐☐☐

Past Pregnancy History – Complete the section *only if* the mother has given consent						
Date of delivery dd – mm – yyyy	**Gestation (weeks)**	**Mode of Delivery**	**Sex**	**Weight (kg)**	**Antenatal Problems**	**Postnatal Problems**
☐☐ ☐☐ ☐☐☐☐	☐☐		☐ Male ☐ Female	☐.☐		
☐☐ ☐☐ ☐☐☐☐	☐☐		☐ Male ☐ Female	☐.☐		
☐☐ ☐☐ ☐☐☐☐	☐☐		☐ Male ☐ Female	☐.☐		

Relevant concomitant medications? ☐ N ☐ Y

Complete the section *only if* the mother has given consent

Only include drugs given before or during pregnancy considered relevant any adverse pregnancy outcome. Use continuation page if necessary.

Continued on separate page? ☐ Y

Drug Name	**Brand**	**Indication**	**Total Daily Dose Prior to Pregnancy Confirmation** (include units)	**Frequency**	**Route**	**Date of First Administration of Drug AND Date of Last Administration of Drug Prior to Pregnancy Outcome** (dd/mm/yyyy)
						First ☐☐ ☐☐ ☐☐☐☐ *Last* ☐☐ ☐☐ ☐☐☐☐
						First ☐☐ ☐☐ ☐☐☐☐ *Last* ☐☐ ☐☐ ☐☐☐☐
						First ☐☐ ☐☐ ☐☐☐☐ *Last* ☐☐ ☐☐ ☐☐☐☐
						First ☐☐ ☐☐ ☐☐☐☐ *Last* ☐☐ ☐☐ ☐☐☐☐

Investigator Assessment: *(must be authorised on staff delegation log to review pregnancies and perform assessment of causal relationship)*

Print Name: _____ **Signature:** _____ **Date of Assessment:** ☐☐ ☐☐ ☐☐☐☐ (*d d m m y y y y*)

Form(s) completed by: *(must be authorised on staff delegation log to complete CRFs and report pregnancies)*

Print Name: _____ **Signature:** _____ **Date of Completion:** ☐☐ ☐☐ ☐☐☐☐ (*d d m m y y y y*)

ANIMATE

PREGNANCY REPORT

Patient trial number: ANM – ☐☐☐

Concomitant medications (Continuation page) **Complete the section *only if* the mother has given consent**
Only include drugs given before or during pregnancy considered relevant any adverse pregnancy outcome.

Drug Name	**Brand**	**Indication**	**Total Daily Dose Prior to Pregnancy Confirmation** (include units)	**Frequency**	**Route**	**Date of First Administration of Drug AND Date of Last Administration of Drug Prior to Pregnancy Outcome** (dd/mm/yyyy)
						First ☐☐ ☐☐ ☐☐☐☐ *Last* ☐☐ ☐☐ ☐☐☐☐
						First ☐☐ ☐☐ ☐☐☐☐ *Last* ☐☐ ☐☐ ☐☐☐☐
						First ☐☐ ☐☐ ☐☐☐☐ *Last* ☐☐ ☐☐ ☐☐☐☐
						First ☐☐ ☐☐ ☐☐☐☐ *Last* ☐☐ ☐☐ ☐☐☐☐
						First ☐☐ ☐☐ ☐☐☐☐ *Last* ☐☐ ☐☐ ☐☐☐☐
						First ☐☐ ☐☐ ☐☐☐☐ *Last* ☐☐ ☐☐ ☐☐☐☐
						First ☐☐ ☐☐ ☐☐☐☐ *Last* ☐☐ ☐☐ ☐☐☐☐
						First ☐☐ ☐☐ ☐☐☐☐ *Last* ☐☐ ☐☐ ☐☐☐☐
						First ☐☐ ☐☐ ☐☐☐☐ *Last* ☐☐ ☐☐ ☐☐☐☐
						First ☐☐ ☐☐ ☐☐☐☐ *Last* ☐☐ ☐☐ ☐☐☐☐