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: _____

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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
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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.
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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
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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.