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