

ANIMATE PATIENT SCREENING LOG

Principal Investigator		Site Name	
-------------------------------	--	------------------	--

Date of Screen (dd/mm/yy)	Patient Initials	Gender (M/F)	Age	Did patient consent to trial? (Y/N)	Main reason for exclusion (use code on reverse)	Comments	Patient recruited to trial? (Y/N)	If recruited, provide trial number	Patient YouTube videos If viewed, did the videos influence the patient decision to join the trial? (Y/N/N/A)

Please make all entries in BLACK ink. Any errors should be crossed out with a single pen stroke, initialled and dated. When starting a new page, please fill in page number in bottom right hand corner.

For UCL CTC use only- File all correspondence relating to queries with this log				
Date received: _____	Date checked: _____	CTC staff member initials: _____	Queries? Y / N	Date queries resolved: _____

Screening Log Instructions

When do I start using the screening Log?

Please begin using the screening log as soon as possible after site activation.

Which patients should I include on the Screening Log?

All patients identified with primary refractory classical Hodgkin Lymphoma or classical Hodgkin Lymphoma in first relapse who are about to receive, receiving or within 14 days of their first two cycles of first or second line salvage therapy (three or four cycles if receiving brentuximab vedotin).

Maintenance of the screening Log.

It is important that completion of this log is undertaken on an ongoing basis rather than retrospectively. It is suggested that potential patients are assessed from clinic lists and at MDT meetings.

What do I do with the logs?

Logs should be emailed (ctc.animate@ucl.ac.uk) to the UCL CTC when requested. Logs can also be used at regular in-house meetings to discuss missed patients and methods to increase accrual.

How do I complete the logs?

Date of screen, patient initials, gender and age should be recorded on the log. The codes below should be used for expressing the main reason for exclusion. If the reason does not fit into one of the categories provided, please enter '17' and specify the reason in the comments section. If the patient is going to participate in the study, please answer **Y** or **N** in the box 'Patient recruited to trial?'

Who should I call if I have any questions or problems?

For further information, please contact ANIMATE Trial Coordinator, email ctc.animate@ucl.ac.uk or call 0207 679 9860

CODES for 'Main reason for exclusion'

Patient Refusal

1. Concern regarding trial treatment
2. Concern regarding scanning requirements
3. Other – specify reason in comments

Protocol Exclusions

4. Not fit for autologous stem cell transplantation
5. Nodular lymphocyte predominant Hodgkin Lymphoma
6. History of colitis, inflammatory bowel disease or pneumonitis
7. Patient has an autoimmune disorder, other than vitiligo, diabetes mellitus type 1, hypo- and hyperthyroidism not requiring immunosuppressive therapy
8. Known active hepatitis B or C infection
9. Known HIV infection
10. History of allergy (including severe/life threatening skin reaction) to monoclonal antibodies, anaphylaxis or uncontrolled allergy
11. Major surgery within 4 weeks prior to registration
12. Myocardial infarction, unstable angina, coronary artery bypass graft, cerebrovascular accident or transient ischaemic attack within the past 6 months
13. Non-haematological malignancy within the past 3 years (not included in exceptions listed in section 6.2.2 of trial protocol)
14. Unwilling to use adequate and effective contraception during, and for 6 months after trial treatment (for female patients of childbearing potential) or 8 months after trial treatment (for male patients with a partner of childbearing potential)
15. Pregnant or breastfeeding

Other Exclusions

16. Geographical or logistical difficulties
17. Other (record reason in comments)

