ANIMATE UK Site Registration Form

Please complete all section of this form and return to UCL CTC with a copy of the PI's CV.

Completion of this form confirms that the site has discussed the trial with all relevant personnel and can comply with the requirements of the trial. On receipt and review of this form, your site will be added to Part C of the IRAS form which will be submitted to the HRA.

Please contact the ANIMATE trial coordinator (ctc.animate@ucl.ac.uk or 0207 679 9860) if you have any questions about study requirements or completing this form.

Section A: Site Details

NHS Trust/Health Board Name:

Address of NHS Trust/Health Board:

Postcode:

Please state the number of hospitals in which Trial activities will be undertaken in **this NHS Trust/Health Board involving the same Principal Investigator.** ☐

Please list all of the hospitals or locations where trial activities will take place in the table below and record what activities will take place (tick relevant box):

Hospital/location Name, Address and Postcode	**Trust Name** (if different)	Giving out PIS	Consenting	Patient registration	IMP treatment	Treatment	Radiology	Translational samples	Follow up visits

Section B: Principal Investigator

Name and Full Title of Principal Investigator:
Telephone number:
Email Address:

In order to participate in the trial, PIs must have experience of giving nivolumab and/or immuno-oncology therapies:
I confirm that I have experience of administering nivolumab and/or immuno-oncology therapies.

By signing below, I confirm that this site is able to comply with:
• Trial treatment, imaging, clinical care, follow up schedules and all requirements of the trial protocol • Requirements of the Research Governance Framework and the Medicines for Human Use (clinical trials) Act (SI 2004/1031), and all amendments • Data collection requirements, including timely CRF submission • Biological sample collection, processing and storage requirements • Obtaining an ARSAC license for the study, and renewing as necessary (PET centres)

Signed (by PI) *Please ensure an up to date, signed & dated copy of PI's CV is returned with form*:
Signed: _____ **Date:** _____

Section C: Pharmacy

Name and Full Title of Lead Pharmacist:
Telephone number:
Email Address:
Name and Full Title of Lead Pharmacist (please complete if more than one Lead Pharmacist):
Telephone number:
Email Address:
Pharmacy delivery address:

By signing below, I confirm that this site is able to comply with:

- Ensuring adequate training of pharmacy staff and that this delegation of duties is recorded on the site staff delegation log.
- Ensuring Nivolumab supplied for the ANIMATE trial is dispensed to eligible ANIMATE trial patients only and not used outside the context of the trial protocol.
- Maintaining an adequate supply of Nivolumab trial stock
- Storing IMP appropriately and reporting any temperature excursions outside the storage conditions specified in the IB/Summary of Drug Arrangements to UCL CTC
- Maintaining appropriate records including accountability for Nivolumab (ordering, receipt, dispensing, reconciliation and destruction of unused medication (on sponsor authorisation)). Copies of relevant accountability logs are to be sent to UCL CTC upon request.

Signed (by Lead Pharmacist):

Signed: _____ **Date:** _____

Section D: Specimen Collection – Tissue Collection

Up to 3 FFPE tumour blocks per patient to be sent to the HMDS:

- Diagnostic biopsy (or, if unavailable, biopsy at first relapse) – required for all registered patients
- Repeat biopsy if patient relapses/progresses after trial treatment
- Repeat biopsy if patient is PET positive at end of trial treatment (if patient consents).

Blocks can be returned upon written request.

Pathology Staff
Name and Full Title of Lead Pathologist
Telephone number:
Email Address:

By signing below, I confirm that this site:	
Agrees to provide archival tumour blocks from diagnostic (or first relapse) biopsy for the trial	
Agrees to provide tumour blocks from repeat biopsies performed where patients relapse after trial treatment.	
Agrees provide tumour blocks from repeat biopsies performed in consenting patients who are PET positive after 8 cycles of treatment	
I confirm that there are systems in place for procuring archival tissue from other hospitals if required	
I agree that tissue blocks provided may be kept by the Sponsor **OR** Please return tissue blocks once trial analysis is complete	☐ ☐

Signed (by Lead Pathologist):
Signed: _____ Date: _____

Section E: Specimen Collection - Blood

Up to 6 peripheral blood samples per patient to be sent to UCL Cancer Institute:

- Prior to treatment cycle 1
- Prior to treatment cycle 2
- Prior to treatment cycle 4
- Prior to treatment cycle 6 (if continue to 8 cycles)
- Prior to treatment cycle 8 (if continue to 8 cycles)
- 1 month post treatment

Staff Responsible for Blood Specimen Collection
Name and Full Title of Lead Contact:
Telephone number:
Email Address:

By signing below, I confirm that this site is able to comply with:
- Procuring blood samples for the trial - Sending to central labs within the timeframes indicated

Signed (by Lead Contact):
Signed: _____ Date: _____

Section F: PET-CT scanning

Up to 3 PET-CT scans to be performed as per trial requirements and sent electronically for central review by the NCRI core laboratory, St Thomas' Hospital, London:

- Within 15-21 days after cycle 2 of first or second line salvage therapy (or cycle 4 if being treated with Brentuximab vedotin)
- Day 11-13 of cycle 4 of Nivolumab
- Day 11-13 of cycle 8 of Nivolumab

Sites will be provided with a detailed scanning manual to assist in performing scans correctly.

PET centres undertaking scanning for the trial must be approved by the NCRI PET core lab team.

☐ Tick if PET-CT scanning will be outsourced to another Trust – leave the rest of this section blank

Staff Responsible for PET-CT scanning for the trial
Name and Full Title of Lead Contact:
Telephone number:
Email Address:

By signing below, I confirm that this site is able to comply with:
- Obtaining an ARSAC license for trial-related PET-CT scanning, and applying for updates as required - PET-CT accreditation processes - Sequential scanning as per trial requirements (scheduling scans as per protocol, correct uptake time, same machine etc)

Signed (by Lead Contact):
Signed: _____ Date: _____

Please send this completed document to:

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

Tel: 020 7679 9860
Fax: 020 7679 9861

E-mail: ctc.animate@ucl.ac.uk

THIS PAGE IS FOR UCL CTC USE ONLY			
Date form received:		Date PI CV received:	
Site Suitability Assessment:			
Site type for this trial	☐ All site activities ☐ Participant Identification Centre ☐ Recruiting Site ☐ Shared Care Site ☐ Follow-up Site		
Outsourcing PET-CT scanning to another Trust (specify Trust)	☐		
NB site cannot be activated unless nominated PET centre is open/ready to open			

PI CV signed, dated & with evidence of GCP training or GCP certificate provided?	Yes		No	
Site fulfils the minimum criteria for participation	Yes		No	
Site history of serious non-compliance checked?	Yes		No	
Site to be added to Part C of the IRAS form?	Yes		No	
HMDS informed whether site happy for blocks to be retained	Yes		No	

Complete where applicable only - For the purpose of this trial, at CTC this Site will be known as:

(Ideally this will be Trust name but for unclear Site set up situations, please discuss with TGL/STC/Regulatory)

Notes:

Checked by (TC/STC):		Date:	
Print Name:		Signature:	