

ANIMATE Pharmacy Procedure for Reporting Temperature Excursions

The following procedure must be followed when a temperature excursion is identified in the storage area at site for Nivolumab supplied for the **ANIMATE** trial.

Please note that there is a different process for reporting temperature excursions in transit - see the Summary of Drug Arrangements for details.

This procedure must be followed even for minor or brief temperature excursions.

For required storage conditions, please refer to the trial Summary of Drug Arrangements and/or the Investigator Brochure (IB).

Procedure

- Quarantine all affected trial stock IMMEDIATELY – do not dispense
- Confirm with the PI (or other member of clinic staff) when the next patient treatment is due
 - If a patient is due to receive treatment imminently, contact the **ANIMATE** Trial Coordinator urgently (0207 679 9860 / ctc.animate@ucl.ac.uk) to discuss possible treatment options while stock is in quarantine – e.g. order additional stock, etc.
- Review records in the pharmacy file to establish whether kit(s) affected have been subject to previous temperature excursions – this information is needed to complete the notification of temperature excursion.
- Complete Section A of the '**ANIMATE** Notification of Temperature Excursion' form, with details of the temperature excursion and the product(s) (including batch and kit number(s)) affected
- Send the '**ANIMATE** Notification of Temperature Excursion' form and a copy of the relevant temperature logs/graphs to CSM and UCL CTC, either by:
 - Email to ca209@csmondemand.com and ctc.excursions@ucl.ac.uk
 - or
 - Fax to +49 6196 5861-111 and 0207 679 9861, marked for the attention of the **ANIMATE** trial
- CSM will review the form and temperature logs/graphs and complete section B of the 'Notification of Temperature Excursion, indicating whether the drug is still viable. This will be returned to pharmacy by email.
 - If CSM confirms that the drug remains viable, remove from quarantine ready for dispensing to patients
 - If CSM confirms that the drug is no longer viable, destroy drug unless instructed otherwise, and order new stock
- UCL CTC will request the site complete an additional incident form to give details of corrective and preventative actions taken
- File the notification of temperature excursion form and associated correspondence in the Pharmacy Site File

It is imperative that patients are not treated with drug affected by temperature excursions until the case has been reviewed by the pharmaceutical company and they have advised whether it is safe to use the drug. To do so may constitute a serious breach.