

Pharmacy Procedure for Reporting Temperature Excursions

The following procedure must be followed when a temperature excursion is identified in the storage area for any IMP supplied for a UCL CTC managed trial.

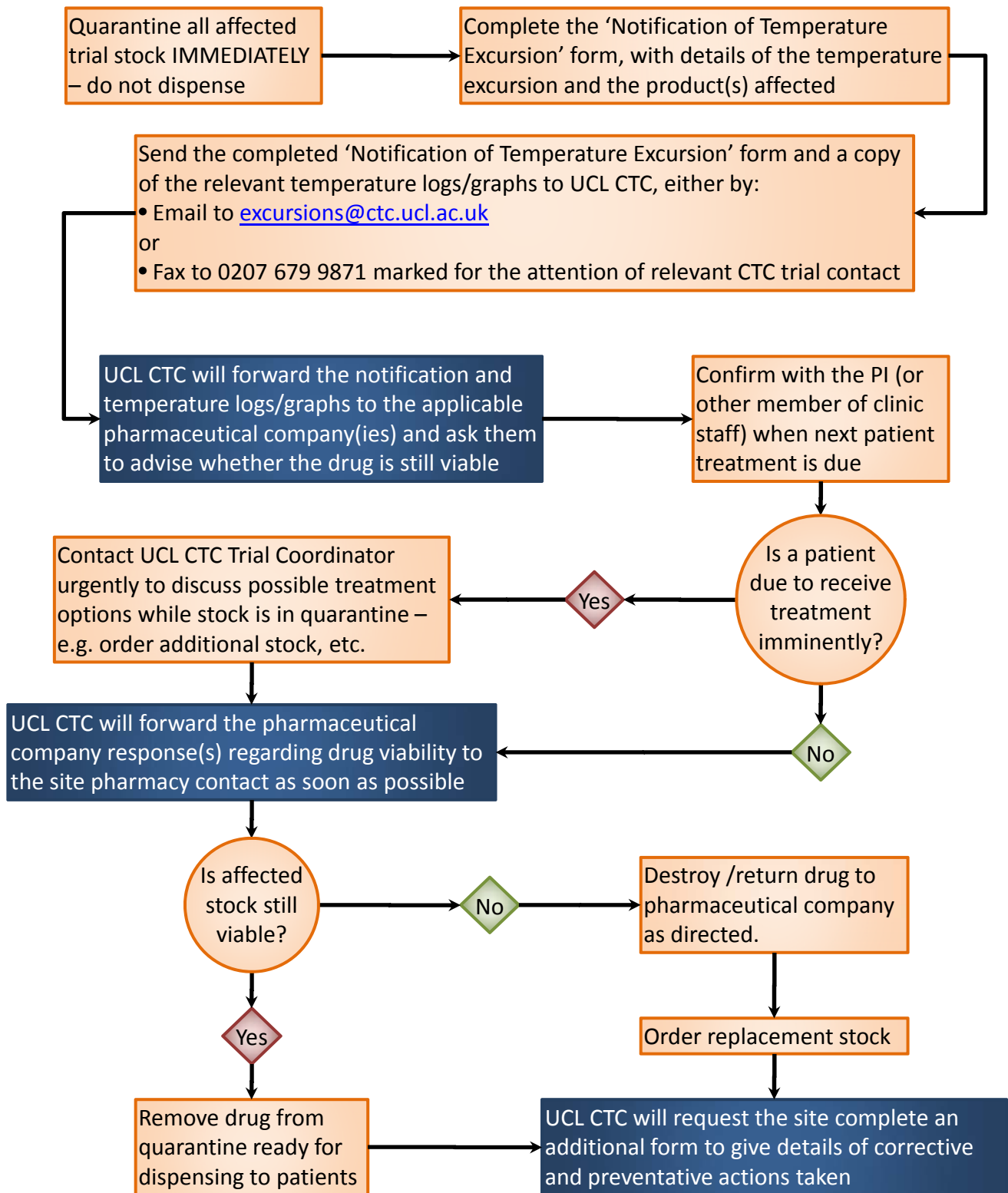
This procedure must be followed even for minor or brief temperature excursions. *[For required storage conditions, please refer to the trial Summary of Drug Arrangements and/or the Investigator Brochure(IB)/Summary of medicinal Product Characteristics(SmPC) for each drug involved]*

Procedure *(please also see associated flowchart)*

- Quarantine all affected trial stock IMMEDIATELY – do not dispense
- Complete the 'Notification of Temperature Excursion' form, with details of the temperature excursion and the product(s) affected
- Send the completed 'Notification of Temperature Excursion' form and a copy of the relevant temperature logs/graphs to UCL CTC, either by:
 - Email to excursions@ctc.ucl.ac.uk
 - or
 - Fax to 0207 679 9871 marked for the attention of relevant CTC trial contact
- UCL CTC will forward the notification and temperature logs/graphs to the applicable pharmaceutical company(ies) and ask them to advise whether the drug is still viable
- Confirm with the PI (or other member of clinic staff) for each affected trial when the next patient treatment is due
 - If a patient is due to receive treatment imminently, contact the UCL CTC Trial Coordinator urgently to discuss possible treatment options while stock is in quarantine – e.g. order additional stock, etc.
- UCL CTC will forward the pharmaceutical company response(s) regarding drug viability to the site pharmacy contact as soon as possible.
 - If it confirms that the drug remains viable, remove from quarantine ready for dispensing to patients
 - If it confirms that the drug is no longer viable, destroy/return drug to pharmaceutical company as directed and order new stock
- UCL CTC will request the site complete an additional form to give details of corrective and preventative actions taken

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 will constitute a serious breach.

Pharmacy Procedure for Reporting Temperature Excursions – Flowchart



Key

- aa Denotes action to be implemented by site pharmacy staff
- aa Denotes action to be implemented by CTC staff