ISRCTN: 97695350



## TICH-3 - Working Practice Document



## Destruction of IMP

TICH-3 treatment packs may become damaged or expire before being used by trial participants.

Once a TICH-3 treatment pack at your site has expired or is damaged, it should be disposed of locally in line with your local trust procedure for destruction of pharmaceutical waste. For damaged vials please also refer to WPD 007 (Broken Vials) for list of actions to take prior to local destruction.

TICH-3 investigators can view the list of treatment packs and determine which are due to expire - or have already expired - by logging into the trial web site and accessing the main participant list, then selecting the link against "Number of available treatment packs" (on the right-hand side of the web page).

Pharmacy are required to update the accountability log, inventory log, and a disposal log (see Appendix 1 for example, use local log if available), plus any other local documentation as required. Treatment Pack ID numbers should be used on all documentation throughout, as opposed to block numbers.

The trial accountability log should be updated (in the comments field) to explain that the treatment pack has expired and the drug has been sent for destruction. Drug already issued to the stroke unit/ward may also expire, therefore please ensure any expired stock is returned to pharmacy and recorded appropriately.

The inventory log should be updated (in the comments field) to state that the treatment pack has expired and the drug has been sent for destruction.

Please ensure that a copy of the destruction log is sent to the trials office once the drug has been destroyed.

Pharmacy should ensure that all the above paperwork is filed in their pharmacy file.

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## Appendix 1 - Example of Drug Destruction Log Site: \_\_\_\_\_Local Investigator: \_\_\_\_ At the request of: Sponsor The following IMP have been destroyed in pharmacy according to local Trust procedure for destruction of pharmaceutical waste. Description Treatment Quantity Batch **Expiry** Pack ID Number Date Destroyed by: \_\_\_\_\_ Date: \_\_\_\_\_ Name (PRINT): \_\_\_\_\_ Title: \_\_\_\_ Date: \_\_\_\_ Date: \_\_\_\_\_# Witnessed by: \_\_\_\_\_ Name (PRINT): \_\_\_\_\_ Title: \_\_\_\_\_ Date: \_\_\_\_\_

1 copy in the pharmacy file