Division of Clinical Neuroscience, Stroke

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**Desmopressin for reversal of Antiplatelet drugs in Stroke due to Haemorrhage (DASH)**

EudraCT Number: 2018-001904-12

IRAS ID:233744

Sponsor Ref:18040

Site Name:………………………………………… Principal Investigator:…………………………………….

**Lead Pharmacist Declaration**

On behalf of the Principal Investigator, I agree to ensure processes are in place to conduct this Trial in accordance with current Good Clinical Practice guidelines, Good Manufacturing Guidelines, the Medicines for Human Use (Clinical Trials) Regulations 2006\* standards and the Clinical Trial Authorisation through adherence to procedures outlined in the current version of the Protocol and Pharmacy Manual.

Specifically, I agree to ensure the following:

* All IMPs are stored and handled according to the Manufacturer’s recommendations as detailed in the current SmPC.
* All temperature excursions are handled in accordance with the Pharmacy Manual.
* All IMPs are fully traceable throughout their use in the trial and records are maintained to allow reconstruction of the movement of each IMP throughout the trial, including recording of batch number.
* Any deviations from the Manufacturers recommendations or Pharmacy Manual are notified to STU.
* All IMPs are labelled in accordance with the Clinical Trial Authorisation (CTA)
* Trial specific accountability logs are maintained for any Desmopressin/Sodium Chloride 0.9% supplied specifically for use in the trial.
* Any Desmopressin/Sodium Chloride 0.9% supplied specifically for the trial is only used for patients registered into the trial, and will not enter generic hospital supplies.
* All trial documentation and correspondence is stored in a central Pharmacy Site File.
* Any additional local trial documentation will be accurately transcribed from the equivalent document provided by the STU.

\* These amend the principal Regulations (Medicines for Human Use (Clinical Trials) Regulations 2004 which implemented Directive 2001/20/EC on the approximation of the laws, regulations and administrative provisions of the Member States relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products in human use

Lead Pharmacist Name: ………………………………………………

Lead Pharmacist Signature :………………………………………….

Date:……………………………..