North Staffordshire NHS
Combined Healthcare
NHS Trust

A Keele University Teaching Trust

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Ref: KH/SOS/PI

Dear Research Site,

Re: **Stroke Oxygen Study. Eudract number: 2006-003479-11**

It has come to our attention that the Clinical Trial Agreement, states the following responsibilities relating to the Investigational Medicinal Product Oxygen, listed in S**CHEDULE 2:** DIVISION OF RESPONSIBILITIES:

- Ensure that Investigational Medicinal Product (IMP) is not used for any purposes other than the conduct of the Study.
- Ensure IMP is provided and labelled in accordance with the Medicines for Human Use (Clinical Trials) Regulations 2004.
- Ensure that IMP is stored in appropriate and secure conditions and that detailed records are maintained regarding its movement from delivery to return/destruction.

However, the MHRA application which was submitted and approved to enable the trial to have a Clinical Trial Authorisation made it clear that although in this study oxygen is classed as an IMP, it is a gas not a drug and is usually delivered via piped oxygen supplies within each hospital from a central storage unit. Therefore, for the Stroke Oxygen Study, the IMP is cannot be stored or labelled separately. Therefore the above responsibilities do not apply to this study.

Kind regards,

Dr Christine Roffe,
Chief Investigator

Dr Karen Hampson,
R & D Manager