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TICH-3 – Working Practice Document

Emergency Unblinding Procedure
No. 006

Clinicians, patients and outcome assessors (Research Nurse and Radiologist) will be blinded to treatment allocation.

In general, there should be no need to unblind the allocated treatment. If an adverse event should develop or some contraindication to antifibrinolytic therapy develop or emerge after randomisation (e.g. seizure or clinical evidence of thrombosis), the trial treatment should simply be stopped.

Unblinding should be done only in those rare cases when the doctor believes that clinical management depends importantly upon knowledge of whether the patient received antifibrinolytic or placebo.

In those few cases when urgent unblinding is considered necessary, the emergency telephone numbers which are given on the TICH-3 trial documents website, and detailed on the Site File contact sheet, should be telephoned. The following information will be required:

- **Site name**
- **Site number**
- **The name of the doctor requesting unblinding**
- **Reason that un-blinding is thought necessary**
- **The treatment pack ID number**
- **Patient Initials**
- **DOB**
- **Sex**
- **Patient trial number**

If appropriate the caller will then be told whether the patient received the active treatment or placebo. The rate of unblinding will be monitored and audited.