



STITCH (Trauma)
Neurosurgical Trials Unit
3-4 Claremont Terrace
Newcastle University
Newcastle upon Tyne
NE2 4AE

Dear

Re:

Patient Address:

This letter is to inform you that was admitted to hospital with a traumatic intracerebral haemorrhage on 18/** and agreed to take part in a multicentre study, funded by the MRC, of early surgical treatment. The purpose of the study is to determine whether a policy of early surgical evacuation of the haematoma in selected patients with traumatic ICH will improve outcome compared to a policy of initial conservative treatment.

We intend to assess survival and functional outcome at 6 months by a postal questionnaire to the patient or to a relative.

We are now contacting you to confirm that is still, or to the best of your knowledge, alive and resident at the above address. This is in order to avoid distress by attempting to contact families of patients who have died. If you are aware of any serious adverse events resulting in death or hospital admission, it would be extremely helpful if you could let us know to help us avoid inappropriate follow-up. Serious Adverse Events must be reported according to UK regulations and according to MRC guidelines of Good Clinical Practice. The definitions of Serious Adverse Events in international clinical trials include the following (regardless of causality):

- Death
- Life threatening event
- Event requiring or prolonging hospitalisation
- Event causing permanent disability

If you know of any of these occurring since experienced the intracerebral haemorrhage please would you complete the enclosed Major Adverse Events form and return it in the enclosed envelope.

Should you have any questions regarding this study please do not hesitate to contact Professor Mendelow or myself at the Neurosurgical Trials Unit.

Thank you in anticipation of your assistance.

Yours sincerely

Professor A David Mendelow
Principal Investigator

Dr Barbara A Gregson
Trial Director