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

Date

Dear

Re: (Patient)

Patient Address:

This letter is to inform you that <patient> (date of birth) has taken part in a research study: STITCH(TRAUMA): Surgical Trial in Traumatic Intracerebral Haemorrhage.

<Patient> was admitted to this hospital with a head injury resulting in an intracerebral haemorrhage (ICH). 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.

<He/She> will be followed up by postal questionnaires at 3, 6 and 12 months for this study as well as any other follow-ups that are deemed to be required for <his/her> condition. The STITCH (Trauma) co-ordinating centre (Newcastle) will contact you prior to follow ups after the head injury to confirm the patient is still, 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. In the meantime, if you were 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

Please find enclosed an information sheet which will give you more information about the study and a Major Adverse Event form.

Should you have any questions regarding this study please do not hesitate to contact Professor Mendelow or myself at the Directorate of Neurosciences, Newcastle General Hospital.

Yours sincerely

Professor A David Mendelow
Principal Investigator

Dr Barbara A Gregson
Trial Director