

# NHS Research Ethics Committee APPLICATION FORM

## PART C: SITE-SPECIFIC ASSESSMENT

*This form should be completed by the Principal Investigator for each site (see glossary)*

*Part C should be completed and sent with relevant enclosures to each NHS Research Ethics Committee or Research & Development (R&D) department which needs to consider site-specific issues. Consult the application procedure on the COREC website.*

*The data in this box is populated from Part A.*

Name of NHS Research Ethics Committee to which application for ethical review is being made:

Eastern MREC

Project Reference number from above REC: 03/5/059

Name of site NHS REC (or R&D department) undertaking site-specific assessment:

Site NHS REC (or R&D Department) Identifier:

Questions C1, C4, C5, C6, C7 and C8 correspond to questions A1, A2, A65, A10, A12 and A13 on main application form respectively and will populate automatically:

### C1. Title of Research. *(Populated from A1)*

Full title: Randomised Evaluation of Surgery with Craniectomy for Uncontrollable Elevation of Intra-Cranial Pressure

Key words: Head injury, intracranial hypertension, decompressive craniectomy

### C2. Who is the Principal Investigator for this study at this site?

Title: First Name/Initials: Last Name:

Post:

Qualifications:

Organisation:

Address:

Postcode:

Email:

Telephone:

Fax:

*A copy of a current CV (maximum 2 pages of A4) for the Principal Investigator(s) must be submitted with application.*

**C3. Indicate the number of trials/projects within the organisation that the local Principal Investigator has been involved with in the previous 12 months:**

**How many are still current (active or recruiting)?**

**Give details of other members of the local research team responsible to the local Principal Investigator**

**i** Title:  First Name/Initials  Last Name:   
 Position:   
 Qualifications:   
 Role in the research team:

**ii** Title:  First Name/Initials  Last Name:   
 Position:   
 Qualifications:   
 Role in the research team:

**iii** Title:  First Name/Initials  Last Name:   
 Position:   
 Qualifications:   
 Role in the research team:

*If there are more members of the local research team, details should be provided at question C18 or on an attached sheet.*

**C4. Chief Investigator. (Populated from A2)**

Title:  Mr  First Name/Initials:  Peter  Last Name:  Hutchinson   
 Post:  Senior Academy Fellow and Honorary Consultant Neurosurgeon   
 Qualifications  BSc(hons), MBBS, PhD, FRCS (Surg Neurol)   
 Organisation:  University of Cambridge   
 Address:  Box 167, Department of Neurosurgery,   
 University of Cambridge, Addenbrooke's Hospital   
 Cambridge   
 Postcode:  CB2 2QQ   
 Email:  pjah2@cam.ac.uk   
 Telephone:  01223336946   
 Fax:  01223216926

**C5. Other relevant reference numbers if known: (Populated from A65)**

Applicant's/organisation's own reference number, e.g. R&D (if available):   
 Sponsor's/protocol number:   
 Funder's reference number:   
 International Standard Randomized Controlled Trial Number:(ISRCTN):   
 European Clinical Trials Database (EUDRACT) Number:   
 Project website:  www.rescueicp.com

**C6. Give a brief synopsis/summary of methods and overview of the planned research. This should include a brief description of how prospective research participants and concerned communities (not necessarily geographical) from which they are drawn have been consulted over the design and details of the research. (Where appropriate a flow chart or diagram should be submitted separately. It should be clear exactly what will happen to the research participant, how many times and in what order.) (Populated from A10.)**

Introduction - the problem to be addressed.

Head Injury is a major cause of morbidity and mortality worldwide. Trauma is the leading cause of death in the first four decades of life with head injury being implicated in at least half the number of cases. In the UK, 1500 per 100,000 of the population attend Accident and Emergency Departments with a head injury per year.

The fundamental pathophysiological process following head injury is the development and propagation of an escalating cycle of brain swelling, increase in intra-cranial pressure (ICP), reduction in blood supply and oxygen delivery, energy failure and further swelling, enhancing brain injury and poor outcome. The aim of this trial is to determine the effectiveness of an operation (decompressive craniectomy) to intercept this cycle, treat brain swelling and improve outcome.

Hypothesis - the principle research questions to be answered

The application of decompressive craniectomy to head injured patients with raised intracranial pressure refractory to medical treatment results in improvement in outcome.

1. Decompressive craniectomy results in an improvement in the Extended Glasgow Outcome Score, compared to optimal medical treatment.
2. Decompressive craniectomy results in an improvement in surrogate endpoint measures (including specific outcome measures (SF-36 questionnaire), control of ICP, time in intensive care and time to discharge from the neurosurgical unit) compared to optimal medical treatment.

The proposed trial

The study will be a randomised trial comparing optimal medical management with surgery (decompressive craniectomy) for the management of intracranial hypertension following head injury, refractory to first-line treatment. The trial will recruit from centres experienced in the intensive care management of head injury.

The inclusion criteria will be patients with head injury, age 10-65 years with an abnormal CT scan, requiring ICP monitoring (Brain Trauma Foundation Guidelines) with raised ICP (>25mmH) refractory to initial medical treatment measures. Patients may have had an immediate operation for a mass lesion but no a "decompressive" craniectomy.

The two arms will be the continuation of optimal medical management versus surgery (decompressive craniectomy). The study evolved as a result of discussions between potential study centres with the aim of providing flexibility in terms of the intensive care management of the patients, yet sufficient protocol discipline to enable the hypothesis to be addressed.

Further details are available in the trial protocol.

**C7. Will the research participants receive any clinical intervention(s) or procedure(s) including taking samples of human biological material over and above that which would normally be considered a part of routine clinical care? (Populated from A12)**

YES

NO

**C8. Will the research participant be subject to any non-clinical research-related intervention(s) or procedure(s)?**  
(Populated from A13)

YES

NO

**C9. Name of NHS or other organisation where the research will take place.**

**C10. Specify the location(s)/department(s) within the NHS or other organisation where the research will take place.**

**C11. How many research participants/samples is it anticipated will be recruited/obtained from this organisation in total?**

**C12. Give details of who will be responsible for obtaining informed consent locally, their qualifications and relevant expertise and training in obtaining consent for research purposes:**

**C13. What local arrangements have been made for participants who might not adequately understand verbal explanations or written information given in English? (e.g. translation, use of interpreters etc.)**

**C14. What arrangements have been made to inform those responsible for the care of the research participants of their involvement in the research?**

**C15. Are the facilities and staffing available locally adequate to perform any necessary procedures or interventions required for the study, and to deal with any unforeseen consequences of these? (This should include consideration of procedures and interventions in both control and intervention arms of a study.)**

YES  NO

Give the information necessary to justify your answer:

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**C16. Give details of a contact point where participants may obtain further information about the study.**

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**Please specify the headed paper to be used for the information sheet.**

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**C17. If there is no Principal Investigator at local level, is there a local individual who is undertaking a task relating to the research?**

YES  NO  Not Applicable

**C18. Do you need to add further information about certain questions in Part C?**

YES  NO

## Part C: Declaration

- The information in this form is accurate to the best of my knowledge and belief and I take full responsibility for it.
- I undertake to abide by the ethical principles underpinning the Declaration of Helsinki, and Good Practice Guidelines on current proper conduct of research.
- If the research is approved I undertake to adhere to the study protocol without unagreed deviation and to comply with any conditions set out in the letter sent by the NHS Research Ethics Committee notifying me of this.
- I undertake to inform the NHS Research Ethics Committee of any changes in the protocol, and to submit annual reports setting out the progress of the research.
- I am aware of my responsibility to be up to date and comply with the requirements of the law and relevant guidelines relating to security and confidentiality of patient or other personal data, including the need to register when necessary with the appropriate Data Protection Officer.
- I understand that research records/data may be subject to inspection for audit purposes if required in future.
- I understand that personal data about me as a researcher in this application will be held by the Research Ethics Committee and its operational managers, and that this will be managed according to the principles established in the Data Protection Act.

**Signature of the local Principal Investigator\***

**Signature** .....

**Date:**

**Print Name:**

*\* The Chief Investigator should sign where there is no local Principal Investigator for the research locality.*

**PART C IS NOW COMPLETE AND SHOULD BE SUBMITTED to the NHS Research Ethics Committee or NHS organisation conducting site-specific assessment**