

MULTI-CENTRE RESEARCH ETHICS COMMITTEE FOR SCOTLAND

Reference: WH/MREC/98/0/48

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17 July 1998

Dear Dr Al-Shahi,

Research Protocol: MREC/98/0/48 - Prospective Population-Based Study of Intracranial Vascular Malformations (IVM's) in Scotland.

Thank you for submitting the amendments previously requested by the Multi Centre Research Ethics Committee for Scotland.

The members of the Committee present agreed that there is now no objection on ethical grounds to the proposed study whose title is given at the head of this letter. I am, therefore, happy to give you our approval to proceed, on the understanding that you will follow the protocol as agreed. The project must be started within 3 years of the date on which MREC approval is given

Please read the notes regarding notification of changes and completion of progress reports at the end of the Response Form carefully, as the MREC requires that they be followed.

You should note that any change to the research protocol should be drawn up as amendment and the approval of the Multi Centre Research Ethics Committee for Scotland obtained.

You will no doubt realise that whilst the Committee has given approval for the study on ethical grounds, it is still necessary for you to obtain approval from the relevant Clinical Directors and/or Chief Executive of the Trusts (or Health Boards/DHAs) in which the work will be done.

It is also your responsibility to ensure any local researcher seeks the approval of the relevant LREC before starting on research. To do this you should submit the appropriate number of copies of the following to the relevant LRECs:

- this letter
- the MREC Application Form
- the attached MREC response form
- Annexe D of the Application Form
- **one** copy of the protocol

Chairman: Professor C Gillis

Vice-Chairman: Professor P Peattie


During the first year after its establishment, the MREC would like to hear your views and experiences while using the new process. Please can you help us by completing the Principal Researcher Evaluation Form and returning it to me at the above address. Your help is also appreciated in ensuring local researchers are sent a Local Researcher Evaluation Form (which you would complete if there are no local researchers) along with the other paperwork required to gain LREC approval. The new system of MRECs will be reviewed at the end of the first year and your comments will help to make sure that appropriate changes are made.

The MREC for Scotland is fully compliant with the International Committee on Harmonisation/Good Clinical Practice (ICH) Guidelines for the Conduct of Trials Involving the Participation of Human Subjects as they relate to the responsibilities, composition, function, operations and records of an Independent Ethics Committee/Independent Review Board. To this end it undertakes to adhere as far as is consistent with its Constitution, to the relevant clauses of the ICH Harmonised Tripartite Guideline for Good Clinical Practice, adopted by the Commission of the European Union on 17 January 1997. The following documents were included on the computer disk containing the guidelines and application form and are available on request:

- Membership List
- Standing Orders
- Statement of Compliance

Yours sincerely,



 **WALTER HUNTER**
Administrator
Multi-Centre Research Ethics Committee for Scotland