NHS Fife NHS Forth Valley NHS Tayside

Fife, Forth Valley & Tayside Research Ethics Service

Fife & Forth Valley Research Ethics Committee
Research Ethics Office
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Dr Rustam Al-Shahi Salman
MRC Clinician Scientist and Honorary Consultant Neurologist
University of Edinburgh
Bramwell Dott Building, DCN
Western General Hospital
EDINBURGH EH4 2XU

Date: 12 December 2008
Your Ref:
Our Ref: **FB/08/S0501/76**
Enquiries to: Miss Fiona Bain
Extension: Ninewells extension 32701
Direct Line: 01382 632701
Email: fionabain@nhs.net

Dear Dr Salman

Full title of study: **Self-assessment of health-related quality of life for adults with intracranial vascular malformations**
REC reference number: **08/S0501/76**

Thank you for your letter of 25 November 2008, responding to the Committee's request for further information on the above research and submitting revised documentation.

The further information has been considered on behalf of the Committee by the Chair.

Confirmation of ethical opinion

On behalf of the Committee, I am pleased to confirm a favourable ethical opinion for the above research on the basis described in the application form, protocol and supporting documentation as revised, subject to the conditions specified below.

Ethical review of research sites

The favourable opinion applies to the research sites listed on the attached form. Confirmation of approval for other sites listed in the application will be issued as soon as local assessors have confirmed they have no objection.

Conditions of the favourable opinion

The favourable opinion is subject to the following conditions being met prior to the start of the study.

Management permission or approval must be obtained from each host organisation prior to the start of the study at the site concerned.

Management permission at NHS sites ("R&D approval") should be obtained from the relevant care organisation(s) in accordance with NHS research governance arrangements. Guidance on applying for NHS permission is available in the Integrated Research Application System or at http://www.rdforum.nhs.uk.

POSITIVE ABOUT DISABLED PEOPLE

Approved documents

The final list of documents reviewed and approved by the Committee is as follows:

Document	Version	Date
Letter of invitation to participant		08 August 2008
Questionnaire: SIVMS Yearly Questionnaire		
Letter from Sponsor		
Covering Letter		08 August 2008
Protocol	1	08 August 2008
Investigator CV		08 August 2008
Application		08 August 2008
Protocol	SAIVMs-2	03 June 2008
Letter to Consultant including patient details form		
Opt Out Form	2	27 November 2008
Response to Request for Further Information		25 November 2008
Participant Consent Form	2	25 November 2008
Participant Information Sheet: Scottish Audit of Intracranial Vascular Malformations (SAIVMs)		
Participant Information Sheet	2	25 November 2008
Letter of invitation to participant		27 November 2008
Letter of invitation to participant	For entry to audit	27 November 2008

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees (July 2001) and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

After ethical review

Now that you have completed the application process please visit the National Research Ethics Website > After Review

You are invited to give your view of the service that you have received from the National Research Ethics Service and the application procedure. If you wish to make your views known please use the feedback form available on the website.

The attached document "After ethical review – guidance for researchers" gives detailed guidance on reporting requirements for studies with a favourable opinion, including:

- Notifying substantial amendments
- Progress and safety reports
- Notifying the end of the study

The NRES website also provides guidance on these topics, which is updated in the light of changes in reporting requirements or procedures.

We would also like to inform you that we consult regularly with stakeholders to improve our service. If you would like to join our Reference Group please email referencegroup@nres.npsa.nhs.uk.

08/S0501/76	Please quote this number on all correspondence

Yours sincerely

Mr Gavin Costa
Chair

Enclosures: "After ethical review – guidance for researchers"
Site approval form

Copy to: Ms Elspeth Currie Edinburgh Clinical Trials Unit

Fife and Forth Valley REC

LIST OF SITES WITH A FAVOURABLE ETHICAL OPINION

For all studies requiring site-specific assessment, this form is issued by the main REC to the Chief Investigator and sponsor with the favourable opinion letter and following subsequent notifications from site assessors. For issue 2 onwards, all sites with a favourable opinion are listed, adding the new sites approved.

REC reference number:	08/S0501/76	**Issue number:**	0	**Date of issue:**	12 December 2008
Chief Investigator:	Dr Rustam Al-Shahi Salman				
Full title of study:	Self-assessment of health-related quality of life for adults with intracranial vascular malformations				

This study was given a favourable ethical opinion by Fife and Forth Valley REC on 12 December 2008. *The favourable opinion is extended to each of the sites listed below. The research may commence at each NHS site when management approval from the relevant NHS care organisation has been confirmed.*

Principal Investigator	*Post*	*Research site*	*Site assessor*	*Date of favourable opinion for this site*	*Notes* (1)
Dr Rustam Al-Shahi Salman	MRC Clinician Scientist and Honorary Consultant Neurologist	NHS Lothian	Fife and Forth Valley REC	12/12/2008	

Approved by the Chair on behalf of the REC:

..... (Signature of ~~Chair~~/Co-ordinator)
(delete as applicable)

..... (Name)

(1) *The notes column may be used by the main REC to record the early closure or withdrawal of a site (where notified by the Chief Investigator or sponsor), the suspension of termination of the favourable opinion for an individual site, or any other relevant development. The date should be recorded.*