

08 October 2004

Dr Drew Provan  
Barts and The London Senior Lecturer in  
Haematology  
Barts and The London  
Department of Haematology  
The Royal London Hospital  
London  
E1 1BB

Dear Dr Provan,

**Full title of study: Establishment of a UK Evans' Syndrome Registry and molecular investigation of potential causative factors**  
**REC reference number: 04/MRE02/49**  
**Protocol number: 1**

Thank you for your letter of 24 September 2004, responding to the Committee's request for further information on the above research.

The further information has been considered on behalf of the Committee by the Chairman, in consultation with one member.

#### **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.

#### **Conditions of approval**

The favourable opinion is given provided that you comply with the conditions set out in the attached document. You are advised to study the conditions carefully.

#### **Approved documents**

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

Document Type: Application  
Version: 2  
Dated:  
Date Received: 29/09/2004

Document Type: Investigator CV  
Version: Dr Provans CV  
Dated: 15/07/2004  
Date Received: 16/07/2004

Document Type: Protocol  
Version: 1  
Dated: 26/07/2004  
Date Received: 26/07/2004

Document Type: Covering Letter  
Version: Letter to Ms Cox from Dr Provan  
Dated: 15/07/2004  
Date Received: 16/07/2004

Document Type: Letter from Sponsor  
Version: Sponsorship Agreement - Barts & the London NHS Trust 2003  
Dated: 14/07/2004  
Date Received: 16/07/2004

Document Type: GP/Consultant Information Sheets  
Version: Letter to GP Version 1.0  
Dated: 15/07/2004  
Date Received: 16/07/2004

Document Type: Participant Information Sheet  
Version: Information for Adults Version 2 dated September 2004  
Dated:  
Date Received: 29/09/2004

Document Type: Participant Consent Form  
Version: 2 dated September 2004  
Dated:  
Date Received: 29/09/2004

Document Type: Response to Request for Further Information  
Version: Letter to Ms Cox from Dr Provan  
Dated: 24/09/2004  
Date Received: 29/09/2004

Document Type: Other  
Version: Summary of Changes to the MREC Application Form  
Dated: 24/09/2004  
Date Received: 29/09/2004

Document Type: Other  
Version: Letter to Dr Provan from Mr Leonard  
Dated: 14/07/2004  
Date Received: 16/07/2004

Document Type: Other  
Version: Evans Syndrome Registry Clinical Proforma Version 1  
Dated: 15/07/2004  
Date Received: 16/07/2004

### **Management approval**

You should arrange for all relevant host organisations to be notified that the research will be taking place, and provide a copy of the REC application, the protocol and this letter.

All researchers and research collaborators who will be participating in the research must obtain management approval from the relevant host organisation before commencing any research procedures. Where a substantive contract is not held with the host organisation, it may be necessary for an honorary contract to be issued before approval for the research can be given.

### **Notification of other bodies**

We shall notify the research sponsor that the study has a favourable ethical opinion.

**Statement of compliance (from 1 May 2004)**

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.

**REC reference number: 04/MRE02/49 Please quote this number on all correspondence**

Yours sincerely,

A handwritten signature in black ink, appearing to read 'Mr Peter Whybrow', written in a cursive style.

**Mr Peter Whybrow  
Chairman**

*Enclosures*

*Standard approval conditions*