

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
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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,



**Mr Peter Whybrow
Chairman**

Enclosures

Standard approval conditions