

National Research Ethics Service

London REC

5L007, L Block
Northwick Park Hospital
Watford Road
Harrow
HA1 3UJ

Telephone: 020 8869 3775
Facsimile: 020 8869 5222

25 September 2007

Dr. Drew Provan
Senior Lecturer in Haematology
Barts and the London,
Queen Mary's School of Medicine and Dentistry
Room 417, Pathology & Pharmacy Building
80 Newark Street
London E1 2ES

Dear Dr. Provan

Full title of study: United Kingdom Adult Idiopathic Thrombocytopenic Purpura (ITP) Registry: An Investigation of Disease Progression, Treatment Effectiveness, and Co-morbid Conditions

REC reference number: 07/H0718/57

Thank you for your letter of 28 August 2007, 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 Chairman, in consultation with two members.

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.

Ethical review of research sites

The Committee has designated this study as exempt from site-specific assessment (SSA). There is no requirement for Local Research Ethics Committees to be informed or for site-specific assessment to be carried out at each site.

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	Version	Date
Application	1	03 July 2007
Investigator CV	Cv for Dr Andrew Provan	03 July 2007
Protocol	1.2	28 August 2007
Covering Letter	Letter to Mr Steiner from Mr Sarpatwari	03 July 2007
Letter from Sponsor	Letter to Dr Provan from Mr Leonard	15 May 2007

Peer Review	ICMS Research Governance Project Form & Peer Reviews	25 April 2007
Statistician Comments	UKITP Statistical Review	
GP/Consultant Information Sheets	Information for Haematologists Version 1.5	28 August 2007
Participant Information Sheet: Information for Prospective Participants	2.1	28 August 2007
Participant Information Sheet: Annual Information Sheet	1.1	03 July 2007
Participant Information Sheet: Six Month Information Sheet	1.1	03 July 2007
Participant Information Sheet: Initial Information Sheet	1.4	03 July 2007
Participant Information Sheet: Information for Past Participants	1.6	03 July 2007
Participant Consent Form: Study Informed Consent Agreement	1.6	28 August 2007
Participant Consent Form: Subsequent Tissue Usage Informed Consent Agreement	1.1	03 July 2007
Response to Request for Further Information	Letter to Dr Steiner from Mr Sarpatwari	28 August 2007
Email to Ms Braley from Mr Sarpatwari		11 July 2007
Letter to Dr Provan from Mr Leonard		20 June 2007
CV for Dr Simon Sanderson		03 July 2007

R&D approval

All researchers and research collaborators who will be participating in the research at NHS sites should apply for R&D approval from the relevant care organisation, if they have not yet done so. R&D approval is required, whether or not the study is exempt from SSA. You should advise researchers and local collaborators accordingly.

Guidance on applying for R&D approval is available from <http://www.rdforum.nhs.uk/rdform.htm>.

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.

Feedback on the application process

Now that you have completed the application process you are invited to give your view of the service you received from the National Research Ethics Service. If you wish to make your views known please use the feedback form available on the NRES website at:

<https://www.nresform.org.uk/AppForm/Modules/Feedback/EthicalReview.aspx>

We value your views and comments and will use them to inform the operational process and further improve our service.

07/H0718/57

Please quote this number on all correspondence

With the Committee's best wishes for the success of this project

Yours sincerely

Louise Braley

**Dr John W Keen
Chairman**

Email: louise.braley@nwlh.nhs.uk

Enclosures:

Standard approval conditions

Copy to:

Mr Gerry Leonard
Barts and The London NHS Trust
Whitechapel
London E1 1BB