

National Research Ethics Service

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31 July 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

The London Research Ethics Committee reviewed the above application at the meeting held on 25 July 2007. The Committee would like to thank Mr Sarpatwari for attending the meeting to discuss the study.

Documents reviewed

The documents reviewed at the meeting were:

Document	Version	Date
Application	1	03 July 2007
Investigator CV	Cv for Dr Andrew Provan	03 July 2007
Protocol	1.1	03 July 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 Reivew	
GP/Consultant Information Sheets	Information for Haematologists Version 1.4	03 July 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 Information Sheet: Information for Prospective Participants	2.0	03 July 2007
Participant Consent Form: Subsequent Tissue Usage Informed Consent Agreement	1.1	03 July 2007

This Research Ethics Committee is an advisory committee to London Strategic Health Authority

The National Research Ethics Service (NRES) represents the NRES Directorate within the National Patient Safety Agency and Research Ethics Committees in England

Participant Consent Form: Study Informed Consent Agreement	1.5	03 July 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

Provisional opinion

Mr Sarpatwari attended the meeting.

The Committee expressed concern that the study as it was presented required site specific assessments (SSAs) to be undertaken. Mr Sarpatwari confirmed that the undertaking of SSAs would hinder the research. It was therefore suggested that the local haematologists should seek consent only to relay details of eligible patients to the chief investigator, who would then send the information sheet and consent form. The information sheet should provide patients with a telephone number and an email address for the research team should the patient have any queries about the study. Patients wishing to participate in the study having read the information sheet could then return the consent form directly to the investigator in a pre-paid self-addressed envelope.

The Committee debated whether the re-consenting of patients who have already consented to take part in the original study was necessary. As the new application differed marginally from the original application, it was agreed that re-consenting patients was not necessary.

It was noted that the answer to question A43 in the application form was contradictory. Mr Sarpatwari confirmed that the Barts and London team would only have access to the patient's notes for monitoring and quality assurance purposes.

Mr Sarpatwari confirmed that double-data entry would only be conducted at the Barts and the London site due to limited resources.

Mr Sarpatwari confirmed that there are no healthy controls to be recruited at present. He confirmed that patients with ITP could be divided into severe and mild categories for comparative purposes.

After discussion, the Committee agreed that it would be content to give a favourable ethical opinion of the research, subject to receiving a complete response to the request for further information set out below.

Authority to consider your response and to confirm the Committee's final opinion has been delegated to the Chairman, in consultation with two members.

Further information or clarification required

- a) In order for the study to be site specific assessment exempt, it was agreed that the local haematologists should seek consent only to relay details of eligible patients to the chief investigator, who would then send the information sheet and consent form. The information sheet should provide patients with a telephone number and an email address for the research team should the patient have any queries about the study. Patients wishing to participate in the study having read the information sheet could then return the consent form directly to the investigator in a pre-paid self-addressed envelope. Could the investigator amend the study documentation accordingly?
- b) Could the investigator clarify what information will be provided to the investigator prior to consent (A26, Application Form)?

Participant Information

It was agreed that the patient information needed to be amended taking into consideration the following:

- a) It was agreed that the information sheet needed to be re-written using lay terminology. For example, words such as "co-morbid disease", "explicitly codified", "information permissible for extraction" and "external validation" should be replaced using lay terminology.
- b) It was agreed that the information sheet should use the same type font throughout.
- c) It was agreed that the information sheet needed to include a section specifically for data protection. It was noted that the information from the first paragraph on page 2 could be included in this section.
- d) It was agreed that the patient information sheet and consent form needed to clarify that the team at Barts and the London would have access to patients' notes for monitoring and quality assurance purposes only.
- e) The sentence "this study will likely not.." should be amended to read "this study is unlikely to..." (page 2).

When submitting your response to the Committee, please send revised documentation where appropriate underlining or otherwise highlighting the changes you have made and giving revised version numbers and dates.

The Committee will confirm the final ethical opinion within a maximum of 60 days from the date of initial receipt of the application, excluding the time taken by you to respond fully to the above points. A response should be submitted by no later than 28 November 2007.

Ethical review of research sites

The Committee agreed that all sites in this study should be exempt from site-specific assessment (SSA). There is no need to submit the Site-Specific Information Form to any Research Ethics Committee. However, all researchers and local research collaborators who intend to participate in this study at NHS sites should seek approval from the R&D office for the relevant care organisation.

Membership of the Committee

The members of the Committee who were present at the meeting are listed on the attached sheet.

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.

07/H0718/57

Please quote this number on all correspondence

Yours sincerely



Dr T. J. Steiner
Chair

Email: louise.braley@nwlh.nhs.uk

Enclosures:

List of names and professions of members who were present at the meeting and those who submitted written comments.

Copy to:

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