



Health Research Authority

NRES Committee London - Central

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02 January 2013

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

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

REC reference: 07/H0718/57

Amendment number: 4

Amendment date: 08 November 2012

IRAS project ID:

The above amendment was reviewed at the meeting of the Sub-Committee held on 24 December 2012.

Ethical opinion

There were no ethical issues discussed.

The members of the Committee taking part in the review gave a favourable ethical opinion of the amendment on the basis described in the notice of amendment form and supporting documentation.

Approved documents

The documents reviewed and approved at the meeting were:

Document	Version	Date
3. UKITP Study Protocol (Tracked Change Version)	2.1	08 November 2012
3. UKITP Study Protocol	2.0	09 February 2012
1. UKITP Readme (Provisionally accepted change version)	2.0	08 November 2012
1. UKITP Read me (Tracked Change Version)	2.0	08 November 2012

1. UKITP Read me	1.9	09 February 2012
Notice of Substantial Amendment (non-CTIMPs)		13 December 2012
Covering Letter		28 November 2012
5. Haematologist Overview	2.0	09 February 2012
4. Prospective Participant Overview (provisionally accepted change version)	3.0	08 November 2012
4. Prospective Participant Overview (Tracked Change Version)	3.0	08 November 2012
4. Prospective Participant Overview	2.9	09 February 2012
3. UKITP Study protocol (provisionally Accepted Change Version)	2.0	08 November 2012
7. Annual Information Sheet	1.6	09 July 2012
6. UKITP Initial Information Sheet (Remodelled Version)	2.3	08 November 2012
6. UKITP Initial Information Sheet	2.2	09 July 2010
5. Haematologist Overview (provisionally accepted change version)	2.3	08 November 2012
5. Haematologist Overview (Tracked Change Version)	2.3	08 November 2012
9. UKITP Subsequent Tissue Usage Informed Consent Agreement	1.4	09 February 2012
8. UKITP Study Informed Consent Agreement (Provisionally Accepted Change Version)	4.2	08 November 2012
8. UKITP Study Informed Consent Agreement (Tracked Change Version)	4.2	08 November 2012
8. UKITP Study Informed Consent Agreement	4.1	09 February 2012
7. Follow Up/Update Information Sheet (Remodelled Version)	1.7	08 November 2012
24. UKITP GP Pro-forma	1.0	08 November 2012
23. UKITP General Practitioner Letter Template	1.0	08 November 2012
9. UKITP Subsequent Tissue Usage Informed Consent Agreement (Provisionally Accepted Change Version)	1.5	08 November 2012
9. UKITP Subsequent Tissue Usage Informed Consent Agreement (Tracked Change Version)	1.5	08 November 2012

Membership of the Committee

The members of the Committee who took part in the review are listed on the attached sheet.

R&D approval

All investigators and research collaborators in the NHS should notify the R&D office for the relevant NHS care organisation of this amendment and check whether it affects R&D approval of the research.

Statement of compliance

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

We are pleased to welcome researchers and R & D staff at our NRES committee members' training days – see details at <http://www.hra.nhs.uk/hra-training/>

07/H0718/57:

Please quote this number on all correspondence

Yours sincerely

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A handwritten signature in cursive script, appearing to read "Kate Donaldson".

Dr John Keen
Chair

E-mail: NRESCommittee.London-Central@nhs.net

Enclosures: List of names and professions of members who took part in the review

Copy to: Mr Gerry Leonard, Barts and The London NHS Trust

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Attendance at Sub-Committee of the REC meeting on 24 December 2012