

London - Central Research Ethics Committee

3rd Floor, Barlow House
4 Minshull Street
Manchester
M1 3DZ

07 July 2017

Dr Dan Hart
Pathology & Pharmacy Building
80 Newark Street
London
SE1 2ES

Dear Dr Hart

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: Substantial Amendment 5

Amendment date: 12 June 2017

IRAS project ID:

This amendment consisted of a change of chief investigator from Dr Drew Provan to Dr Dan Hart also requested a year extension to the study to allow further recruitment.

The above amendment was reviewed by the Sub-Committee held by correspondence.

Ethical opinion

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.

The members of the Sub-Committee raised no ethical concerns regarding this amendment and were content to issue a Favourable Opinion.

Approved documents

The documents reviewed and approved at the meeting were:

<i>Document</i>	<i>Version</i>	<i>Date</i>
Covering letter on headed paper [signed Dr Provan]		28 April 2017
GP/consultant information sheets or letters [Clean/Tracked]	1.1	22 February 2017
GP/consultant information sheets or letters [Proforma Clean/Tracked]	1.1	22 February 2017
Notice of Substantial Amendment (non-CTIMP) [signed by sponsor]	Substantial Amendment 5	12 June 2017
Other [Declaration signed Dr Hart]		27 April 2017
Other [Certificate Good Clinical Practice]		13 July 2016
Other [Instructions for filing]		22 February 2017

Other [Hematologist overview]	2.4	22 February 2017
Participant consent form [Clean/Tracked]	4.3	22 February 2017
Participant consent form [Subsequent Tissue Usage Clean/Tracked]	1.6	22 February 2017
Participant information sheet (PIS) [Follow up - Clean/Tracked]	1.8	22 February 2017
Participant information sheet (PIS) [Initial assessment - clean/tracked]	2.4	22 February 2017
Participant information sheet (PIS) [Prospective patient - clean/tracked]	3.1	22 February 2017
Research protocol or project proposal [Clean/Tracked]	2.2	22 February 2017
Summary CV for Chief Investigator (CI) [Dr Hart]		01 January 2017

Membership of the Committee

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

Working with NHS Care Organisations

Sponsors should ensure that they notify the R&D office for the relevant NHS care organisation of this amendment in line with the terms detailed in the categorisation email issued by the lead nation for the study.

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 Research Ethics Committee members' training days – see details at <http://www.hra.nhs.uk/hra-training/>

07/H0718/57:	Please quote this number on all correspondence
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Yours sincerely



pp
Dr Andrew Hilson
Chair

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

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

London - Central Research Ethics Committee

Attendance at Sub-Committee of the REC meeting on 23 June 2017

Committee Members:

<i>Name</i>	<i>Profession</i>	<i>Present</i>	<i>Notes</i>
Mr Clive Carsley	Retired Lawyer	Yes	
Dr Andrew Hilson	Consultant in Nuclear Medicine	Yes	Chair

Also in attendance:

<i>Name</i>	<i>Position (or reason for attending)</i>
Ms Julie Acourt	REC Assistant