

London - Central Research Ethics Committee

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

Please note: This is the favourable opinion of the REC only and does not allow the amendment to be implemented at NHS sites in England until the outcome of the HRA assessment has been confirmed.

19 July 2018

Atiqa Miah
UK ITP Registry
Barts Health NHS Trust
The Royal London Hospital
Pathology and Pharmacy Building
80 Newark Street,
London
E1 2ES

Dear Atiqa Miah

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 6
Amendment date:	18 May 2018
IRAS project ID:	4961

This amendment consisted of a change of Chief investigator, removal of the option to consent via invitation pack from the registry team at the Royal London Hospital, consent will be taken by the local site, GP data collection and entry to be done by the local site rather than the registry team, addition of the pregnancy database with Dr Sue Robinson as sub-investigator for this section, simplification of the number of forms and information sheets, reduction in amount of blood to be collected and patients from the Royal London Hospital only will be invited to take part in a sub-study looking at platelet functionality and immunological profiling.

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 noted some errors in the Patient Information Sheets and asked for these to be corrected, the researcher sent in corrected forms and the Committee were content with the changes.

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		16 May 2018
GP/consultant information sheets or letters [GP letter template]		16 May 2018
Notice of Substantial Amendment (non-CTIMP) [signed D Hart]		18 May 2018
Other [Centre Delegation Log]		16 May 2018
Other [GP proforma]	1.2	16 May 2018
Other [Initial data collection sheet]	2.5	16 May 2018
Other [Local Participant Log]		16 May 2018
Other [Pregnancy Registration Sheet]	1.0	16 May 2018
Other [Pregnancy status and outcome sheet]	1.0	16 May 2018
Other [V McDonald GCP refresher certificate]		16 May 2018
Other [Follow up data collection sheet]	1.9	
Other [Declaration CI signed]		13 July 2018
Participant consent form [Control]	1.0	16 May 2018
Participant consent form [Pregnancy study informed consent]	1.0	16 May 2018
Participant information sheet (PIS) [Prospective Control Participant overview]	1.0	16 May 2018
Participant information sheet (PIS) [Pregnancy prospective participant overview]	1.0	16 May 2018
Participant information sheet (PIS) [prospective participant overview]	3.2	16 May 2018
Research protocol or project proposal	2.3	16 May 2018
Summary CV for Chief Investigator (CI) [Vickie McDonald]		16 May 2018

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.

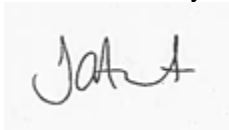
Statement of compliance

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: NRESCCommittee.London-Central@nhs.net

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

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Attendance at Sub-Committee of the REC meeting on 13 July 2018

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