

London - Central Research Ethics Committee

3rd Floor, Barlow House
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13 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:
Amendment date: 18 May 2018
IRAS project ID: 4961

Thank you for submitting the above amendment, which was received on 19 June 2018. I can confirm that this is a valid notice of a substantial amendment and will be reviewed by the Sub-Committee of the REC at its next meeting.

Documents received

The documents to be reviewed are as follows:

<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) [Pregnancy Prospective Participant overview]	1.0	16 May 2018
Participant information sheet (PIS) [Prospective Control Participant overview]	1.0	16 May 2018
Participant information sheet (PIS) [Prospective Participant overview - tracked]	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

Notification of the Committee's decision

The Committee will issue an ethical opinion on the amendment within a maximum of 35 days from the date of receipt.

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 for the research.

We are pleased to welcome researchers and R & D staff at our Research Ethics Service 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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