



# Health Research Authority

## London - Central Research Ethics Committee

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M1 3DZ

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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**REC Assistant**

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