

MIAH, Haroon (BARTS HEALTH NHS TRUST)

From: londoncentral.rec@hra.nhs.uk <noreply@harp.org.uk>
Sent: 22 September 2021 11:14
To: REGISTRYTEAM, Uk-Itp (BARTS HEALTH NHS TRUST);
research.governance@qmul.ac.uk
Subject: IRAS 92703. Substantial Amendment valid for REC review

Follow Up Flag: Follow up
Flag Status: Flagged

Dear Mays,

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

IRAS project ID:

92703

Amendment number:

Substantial amendment 7

Amendment date:

07 September 2021

Thank you for submitting the above amendment, which was received on 21/09/2021. I can confirm that this is a valid notice of a substantial amendment and will be reviewed by the sub committee at its next meeting.

Documents received

The documents to be reviewed are as follows:

<i>Document</i>	<i>Version</i>	<i>Date</i>
Completed Amendment Tool [8. SA 7 Amendment tool LOCKED 20.09.2021]	1.5	07 September 2021
Covering letter on headed paper [6. UKITPR Substantial Amendment 7_Cover Letter]	1	11 August 2021
Other [Protocol Signature page]	4.0	07 September 2021
Other [4. UKITPR Initial Data Collection Sheet v3.0_tracked]	3.0	07 September 2021
Other [4. UKITPR Initial Data Collection Sheet v3.0_clean]	3.0	07 September 2021

Other [5. UKITPR Follow-up Information Sheet v3.0_tracked]	3.0	07 September 2021
Other [5. UKITPR Follow-up Information Sheet v3.0_clean]	3.0	07 September 2021
Participant consent form [3. UKITPR Study Informed Consent Agreement v6.0_Tracked changes]	6.0	07 September 2021
Participant consent form [3. UKITPR Study Informed Consent Agreement v6.0_clean]	6.0	07 September 2021
Participant information sheet (PIS) [2. UKITPR Patient Information Sheet v5.0_Tracked changes]	5.0	07 September 2021
Participant information sheet (PIS) [2. UKITPR Patient Information Sheet v5.0_clean]	5.0	07 September 2021
Research protocol or project proposal [1. UKITPR Study Protocol v4.0_Tracked changes]	4.0	07 September 2021
Research protocol or project proposal [1. UKITPR Study Protocol v4.0_clean]	4.0	07 September 2021

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.

Kind regards

Matthew Mills

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

E. londoncentral.rec@hra.nhs.uk

W. www.hra.nhs.uk

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