

MIAH, Haroon (BARTS HEALTH NHS TRUST)

From: londoncentral.rec@hra.nhs.uk <noreply@harp.org.uk>
Sent: 26 September 2023 14:17
To: REGISTRYTEAM, Uk-Itp (BARTS HEALTH NHS TRUST)
Cc: research.amendments@qmul.ac.uk
Subject: IRAS 92703. Substantial Amendment valid for REC review

Follow Up Flag: Follow up
Flag Status: Flagged

This message originated from outside of NHSmail. Please do not click links or open attachments unless you recognise the sender and know the content is safe.

Dear Dr Chen,

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 8

Amendment date:

01 August 2023

Thank you for submitting the above amendment, which was received on 26/09/2023 . 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 [92703_SA8_Locked21092023]	1.6	21 September 2023
Other [11. UKITPR Initial Data Collection Sheet v5.0_tracked]	5.0	01 August 2023
Other [12. UKITPR Initial Data Collection Sheet v5.0_clean]	5.0	01 August 2023

Other [13. UKITPR Follow-up Information Sheet v5.0_tracked]	5.0	01 August 2023
Other [14. UKITPR Follow-up Information Sheet v5.0_clean]	5.0	01 August 2023
Other [15. UKITPR Pregnancy Registration Sheet 3.0_tracked]	3.0	01 August 2023
Other [16. UKITPR Pregnancy Registration Sheet 3.0_clean]	3.0	01 August 2023
Other [17. UKITPR Pregnancy Status and Outcome Sheet 3.0_tracked]	3.0	01 August 2023
Other [18. UKITPR Pregnancy Status and Outcome Sheet 3.0_clean]	3.0	01 August 2023
Other [19. UKITPR Secondary ITP Initial Data Collection Sheet v2.0_tracked]	2.0	01 August 2023
Other [20. UKITPR Secondary ITP Initial Data Collection Sheet v2.0_clean]	2.0	01 August 2023
Other [21. UKITPR Secondary ITP Follow Up Data Collection Sheet v2.0_tracked]	2.0	01 August 2023
Other [22. UKITPR Secondary ITP Follow Up Data Collection Sheet v2.0_clean]	2.0	01 August 2023
Other [23. UKITPR Invitation letter to participant and remote consenting v2.0_tracked]	2.0	01 August 2023
Other [24. UKITPR Invitation letter to participant and remote consenting v2.0_clean]	2.0	01 August 2023
Other [25. UKITPR Invitation letter to participant and remote consenting v2.0 - Pregnancy registry_tracked]	2.0	01 August 2023
Other [26. UKITPR Invitation letter to participant and remote consenting v2.0 - Pregnancy registry_clean]	2.0	01 August 2023
Other [27. UKITPR Centre Delegation Log v2_tracked]	2.0	01 August 2023
Other [28. UKITPR Centre Delegation Log v2_clean]	2.0	01 August 2023
Other [UKITPR Study Protocol v5.0_clean_signed]	5.0	01 August 2023
Other [GCP_2023.04.20 - Frederick Chen]	N/A	20 April 2023
Other [IRAS Form - New CI]		25 September 2023
Participant consent form [7. UKITPR Study Informed]	7.0	01 August 2023

Consent Agreement v7.0_tracked]		
Participant consent form [8. UKITPR Study Informed Consent Agreement v7.0_clean]	7.0	01 August 2023
Participant consent form [9. UKITPR Pregnancy Study Informed Consent Agreement 2.0_tracked]	2.0	01 August 2023
Participant consent form [10. UKITPR Pregnancy Study Informed Consent Agreement 2.0_clean]	2.0	01 August 2023
Participant information sheet (PIS) [3. UKITPR Patient Information Sheet v6.0_tracked]	6.0	01 August 2023
Participant information sheet (PIS) [4. UKITPR Patient Information Sheet v6.0_clean]	6.0	01 August 2023
Participant information sheet (PIS) [5. UKITPR Pregnancy Participant Information Sheet 3.0_tracked]	3.0	01 August 2023
Participant information sheet (PIS) [6. UKITPR Pregnancy Participant Information Sheet 3.0_clean]	3.0	01 August 2023
Research protocol or project proposal [1. UKITPR Study Protocol v5.0_tracked]	5.0	01 August 2023
Research protocol or project proposal [2. UKITPR Study Protocol v5.0_clean]	5.0	01 August 2023
Summary CV for Chief Investigator (CI) [CV_2023.06.06 - Fred Chen]	N/A	06 June 2023

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

Ali Hussain

Approvals Administrator

3rd Floor 3 Piccadilly Place | London Road | HRA Manchester Centre | M1 3BN

T. 020 7104 8077

E. londoncentral.rec@hra.nhs.uk

W. www.hra.nhs.uk

Sign up to receive our newsletter [HRA Latest.](#)