

London - Central Research Ethics Committee

3rd Floor 3 Piccadilly Place
London Road
Manchester
M1 3BN

**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.**

09 October 2023

Dr Frederick Chen
Barts Health NHS Trust
4th Floor Pathology and Pharmacy Building
Department of Clinical Haematology
Pathology & Pharmacy Building
80 Newark Street
London E1 2ES

Re-issued

Dear Dr Chen

| | |
|--------------------------|--|
| Study title: | United Kingdom Adult Immune ThrombocytoPenia (ITP) Registry: An Investigation of Disease Progression, Treatment Effectiveness, and Co-morbid Conditions |
| REC reference: | 07/H0718/57 |
| Amendment number: | Substantial amendment 8 |
| Amendment date: | 01 August 2023 |
| IRAS project ID: | 92703 |

The above amendment was reviewed by the Sub-Committee in 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.

Approved documents

The documents reviewed and approved at the meeting were:

| <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 Consent Agreement v7.0_tracked] | 7.0 | 01 August 2023 |
| 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] | 5.0 | 01 August 2023 |

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|---|-----|----------------|
| v5.0_tracked] | | |
| 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 |

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.

Amendments related to COVID-19

We will update your research summary for the above study on the research summaries section of our website. During this public health emergency, it is vital that everyone can promptly identify all relevant research related to COVID-19 that is taking place globally. If you have not already done so, please register your study on a public registry as soon as possible and provide the HRA with the registration detail, which will be posted alongside other information relating to your project.

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.

HRA Learning

We are pleased to welcome researchers and research staff to our HRA Learning Events and online learning opportunities— see details at: <https://www.hra.nhs.uk/planning-and-improving-research/learning/>

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| IRAS Project ID - 92703: | Please quote this number on all correspondence |
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Yours sincerely

Pp *Ali Hussain*

Dr Susan Grieve
Chair

E-mail: londoncentral.rec@hra.nhs.uk

London - Central Research Ethics Committee

Attendance at Sub-Committee of the REC meeting on 12 October 2023

Committee Members:

| <i>Name</i> | <i>Profession</i> | <i>Present</i> | <i>Notes</i> |
|------------------|-----------------------------|----------------|--------------|
| Dr Susan Grieve | Pharma & Biotech Consultant | Yes | Chair |
| Miss Kate Larard | Medical Undergraduate | Yes | |

Also in attendance:

| <i>Name</i> | <i>Position (or reason for attending)</i> |
|----------------|---|
| Mr Ali Hussain | Approvals Administrator |