

Health and Social Care Research Ethics Committee B (HSC REC B)

23 June 2025

Prof Mark H Wilson
Consultant Neurosurgeon
Imperial College Healthcare NHS Trust
St Mary's Hospital
Praed Street
London
W2 1NY

Dear Prof Wilson

Study title: Randomised controlled trial of the clinical and cost-effectiveness of cervical spine immobilisation following blunt trauma (SIS trial)

REC reference: 22/NI/0173

Protocol number: 22IC7925

Amendment number: Substantial Amendment 02

Amendment date: 19 June 2025

IRAS project ID: 316755

The above amendment was reviewed at the meeting of the Sub-Committee held on 23 June 2025 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 [316755_Amendment_Tool_SA_002_19May2025]	N/A	19 May 2025
Covering letter on headed paper [SIS - RECHRA Substantial Amendment 02 Cover Letter]	N/A	06 June 2025
Participant consent form [SIS_PatientConsentForm_v4.0_16May2025_Tracked changes]	4.0	16 May 2025
Participant consent form [SIS_PatientConsentForm_v4.0_16May2025_Clean]	4.0	16 May 2025
Participant consent form [SIS_ParentGuardianDeclarationForm_v2.0_16May2025_Tracked Changes]	2.0	16 May 2025
Participant consent form [SIS_ParentGuardianDeclarationForm_v2.0_16May2025_Clean]	2.0	16 May 2025

Participant consent form [SIS_ConsulteeDeclarationForm_v3.0_16May2025_Tracked Changes]	3.0	16 May 2025
Participant consent form [SIS_ConsulteeDeclarationForm_v3.0_16May2025_Clean]	3.0	16 May 2025
Participant consent form [SIS_OptOutForm_v1.0_16May2025_Clean]	1.0	16 May 2025
Participant information sheet (PIS) [SIS_AdultPIS_v3.0_16May2025_tracked changes]	3.0	16 May 2025
Participant information sheet (PIS) [SIS_AdultPIS_v3.0_16May2025_Clean]	3.0	16 May 2025
Participant information sheet (PIS) [SIS_ParentGuardianPIS_v3.0_16May2025_Tracked changes]	3.0	16 May 2025
Participant information sheet (PIS) [SIS_ParentGuardianPIS_v3.0_16May2025_Clean]	3.0	16 May 2025
Participant information sheet (PIS) [SIS_YoungPersonPIS_v2.0_16May2025_Tracked changes]	2.0	16 May 2025
Participant information sheet (PIS) [SIS_YoungPersonPIS_v2.0_16May2025_Clean]	2.0	16 May 2025
Research protocol or project proposal [SIS_Protocol_v7.0_16May2025_tracked changes]	7.0	16 May 2025
Research protocol or project proposal [SIS_Protocol_v7.0_16May2025_Clean]	7.0	16 May 2025

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/>

IRAS Project ID - 316755:

Please quote this number on all correspondence

Yours sincerely

Denise Nesbitt

p.p

Dr Aaron Courtenay

Vice-Chair

E-mail: recb@hscni.net

Enclosures:

List of names and professions of members who took part in the review

Copy to:

Mr Keith Boland, Imperial College Healthcare NHS Trust

HSC REC B

Attendance at Sub-Committee of the REC meeting on 23 June 2025

Committee Members:

<i>Name</i>	<i>Profession</i>	<i>Present</i>	<i>Notes</i>
Dr Aaron Courtenay (Chaired the meeting)	Pharmacist	Yes	
Dr Samantha Stewart	N.I Civil Servant	Yes	

Also in attendance:

<i>Name</i>	<i>Position (or reason for attending)</i>
Mrs Denise Nesbitt	REC B Manager (Minutes)