SIS - REC/HRA Substantial Amendment 02 Cover Letter

Health and Social Care Research Ethics Committee B (HSC REC B)
Office for Research Ethics Committees Northern Ireland (ORECNI)
Lissue Industrial Estate West,
5 Rathdown Walk,
LISBURN,
BT28 2RF

6 June 2025

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
IRAS project ID:	316755

Dear HSC REC B

I am writing to you in relation to substantial amendment 02 for the above-mentioned trial. The following changes to the trial have been detailed in the amendment tool. Please see below for further clarification on the changes and reasons for these changes.

1) Change in sample size from 8316 down to 2010
2) Change in consent process to add in an 'Opt-out' consent model
3) Change to the protocol v7.0, 16May2025 for the following reasons:
Following completion of the pilot extension phase and Data Monitoring Committee (DMC)/ Trial Steering Committee (TSC) meetings with discussions with funder there are now 3 main changes in the study
1. Change in sample size for main study (now 2010 previously 8316)
2. Change in the FIM-score cut-off from 2 point to 3 points for analysis.
3. Change in Consent process - Now utlising an opt out consent procedure detailed for those patients who are lost at discharge similar to other emergency care trials (non-contactable for consent despite 3 contact attempt phone calls).
4) Other minor change to study documents (The following documents have been updated to include the wording on the opt out consent model)
- SIS Young Person PIS V2.0, 16May2025
- SIS Adult PIS V3.0, 16May2025
- SIS Parent Guardian PIS V3.0, 16May2025
Minor updates to consent wording (due to queries from sites, updated to ensure all consent forms were in line with each other)

Clinical Trials Unit – SIS Trial
The University of Warwick
Coventry CV4 7AL, UK
T +44 (0) 2476573005
warwick.ac.uk

- SIS Consultee Declaration Form V3.0, 16May2025
- SIS ParentGuardianDeclarationForm_v2.0, 16May2025
- SIS PatientConsentForm_v4.0, 16May2025

5)Other significant change to study documents (New form created)

- SIS-Opt-Out Form V1.0, 16May2025

Proposal:

The study will continue as previous with verbal agreement (assent) at the time of randomisation in the pre-hospital phase. In hospital, attempt to gain consent for follow-up will continue, as will telephone consent when this has not occurred. In those for whom consent is not possible (due to being discharged early), we will send them an "opt out" form. If this is not returned, we will assume consent for the period of hospitalisation (non-follow up data) and the data from this (e.g. that their c-spine was cleared, and they returned home neurologically the same i.e. the FIM score was unchanged) will be included in the study. We already mentioned in previous versions of the protocol under section 3.2 that for our primary outcome (FIM at discharge) -'If participants are discharged from the emergency department before a member of the local research team has had the opportunity to collect this data, their FIM-motor score will be recorded as 7 (score for total independence)'. Of course, for any data collection post discharge (including all the follow-up sessions) this will involve trial staff continuing to phone the patient and collecting this data upon successful contact and reminding the participant of their right to withdraw at any time.

With regards to the opt-out consent process this was based on the precedence set by prior emergency care trials that members of our team and TSC chair have worked on and will only apply to the patients who have been discharged early.

Precedence:

AHEAD: https://bmjopen.bmj.com/content/7/1/e014324

SHED: https://emj.bmj.com/content/emermed/early/2024/09/12/emermed-2024-214068.full.pdf

ACS-ED: 01.-ACS-ED-Study-Protocol-V2.4-31.01.2023-1.docx

Kind Regards

Christina May (On behalf of the Chief Investigator - Prof Mark Wilson)

Clinical Trial Manager

Clinical Trials Unit – SIS Trial
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Coventry CV4 7AL, UK
T +44 (0) 2476573005
warwick.ac.uk