

South Central - Oxford C Research Ethics Committee

Health Research Authority
2 Redman Place, Stratford, London
E20 1JQ

**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.**

19 May 2025

Dr Laura Green

Principal Investigator in Transfusion Research and Innovation (NHS Blood and Transplant),
Consultant Haematologist in Haemostasis and Transfusion Medicine (Bart's Health NHS
Trust) in
NHS Blood and Transplant & Bart's Health NHS Trust
NHS Blood and Transplant Colindale
Charcot Road
London
NW9 5BG

Dear Dr Green

Study title:	A Multi-Centre Randomised Controlled Trial of the Clinical and Cost Effectiveness of Pre-Hospital Whole Blood Administration versus Standard Care for Traumatic Haemorrhage
REC reference:	22/SC/0072
Protocol number:	v1.0
EudraCT number:	2021-006876-18
Amendment number:	Substantial Amendment 8 (Amendment 10)
Amendment date:	17 February 2025
IRAS project ID:	300414

The above amendment was reviewed at the meeting of the Sub-Committee held on 18 April 2025 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 [300414_Substantial Amendment 8 (Amendment 10)_.pdf]	v1.0	17 February 2025
Cover Letter [SWIFT_ Cover letter AM010_v1.0_2025 02 17.pdf]	v1.0	08 April 2025
Other [CAG_Amendment_request_SWIFT 22 CAG 0050 Amendment 10_17 02 2024_LG.pdf]	v1.0	17 February 2025
Research protocol or project proposal [SWIFT Trial Protocol_v3.1_2025 02 17_TRACKED CHANGES.pdf]	3.1	17 February 2025
Research protocol or project proposal [SWIFT Trial Protocol_v3.1_2025 02 17_CLEAN.pdf]	3.1	17 February 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

This Committee is recognised by the United Kingdom Ethics Committee Authority under the Medicines for Human Use (Clinical Trials) Regulations 2004, and is authorised to carry out the ethical review of clinical trials of investigational medicinal products.

The Committee is fully compliant with the Regulations as they relate to ethics committees and the conditions and principles of good clinical practice.

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 - 300414:	Please quote this number on all correspondence
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Yours sincerely

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Miss Stephanie Ellis
Chair

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

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

Copy to: Ms Joanne Lucas, NHS Blood and Transplant Confidentiality Advise Team

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Attendance at Sub-Committee of the REC meeting on 18 April 2025

Committee Members:

<i>Name</i>	<i>Profession</i>	<i>Present</i>	<i>Notes</i>
Dr Lee Potiphar	Assistant Professor in Adult Nursing and Learning Support Lead	Yes	
Mr Ioan Wigley	Regulatory Affairs Manager	Yes	