

South Central - Oxford C Research Ethics Committee

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

Tel: 0207 104 8271

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.

23 May 2024

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 06
Amendment date:	29 April 2024
IRAS project ID:	300414

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 [300414_Substantial Amendment 06_.pdf]	1.0	29 April 2024
Other [SWiFT_Consent letter after discharge - Parent Guardian_v1.0_2024_03_12.pdf]	1.0	12 March 2024
Other [Splitting of Activities from full SoECAT.docx]	1.2	20 July 2022
Participant consent form [SWiFT-Consent letter ineligible - Patient]	1.1 clean	17 May 2024
Participant consent form [SWiFT_Consent letter ineligible - Personal LR]	1.1 clean	17 May 2024
Participant consent form [SWiFT-Consent letter ineligible - Patient]	1.1 tracked	17 May 2024
Participant consent form [SWiFT_Consent letter ineligible - Personal LR]	1.1 tracked	17 May 2024
Participant information sheet (PIS) [SWiFT Professional LR Information Sheet_v1.0_2024 03 12.pdf]	1.0	12 March 2024
Research protocol or project proposal [SWiFT Trial Protocol]	2.1 clean	17 May 2024
Research protocol or project proposal [SWiFT Trial Protocol]	2.1 tracked	17 May 2024
Schedule of Events or SoECAT [SoECAT Tool A_SWiFT SITE TYPE 1 - AIR AMBULANCE_Updated_24-06-2022.xlsx]	2.0	20 July 2022
Schedule of Events or SoECAT [SoECAT Tool A_SWiFT SITE TYPE 2 - TF LABORATORY_Updated_24-06-2022.xlsx]	1.2	20 July 2022
Schedule of Events or SoECAT [SoECAT Tool A_SWiFT SITE TYPE 3 - RECEIVING HOSPITAL_Updated_24-06-2022.xlsx]	1.2	20 July 2022
Schedule of Events or SoECAT [SoECAT Tool A_SWiFT SITE TYPE 4 - TF LABORATORY AND RECEIVING HOSPITAL_Updated_24-06-2022.xlsx]	1.2	20 July 2007

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.

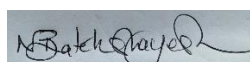
HRA Learning

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

Yours sincerely



pp

Dr Lee Potiphar
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 via correspondence.

Committee Members:

<i>Name</i>	<i>Profession</i>	<i>Present</i>	<i>Notes</i>
Dr Colin Cowan	Locum Consultant Psychiatrist	Yes	
Dr Lee Potiphar Chair	Assistant Professor in Adult Nursing and Learning Support Lead	Yes	

Also in attendance:

<i>Name</i>	<i>Position (or reason for attending)</i>
Nina Bakhshayesh	Approvals Administrator