



Health Research Authority
South Central - Oxford C Research Ethics Committee

Health Research Authority
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07 December 2023

Ms Joanne Lucas
Clinical Operations Manager
NHS Blood and Transplant
NHS Blood and Transplant Clinical Trials Unit
Long Road
Cambridge
CB20PT

Dear Ms Lucas

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: Amendment 05

Amendment date: 16 October 2023

IRAS project ID: 300414

Thank you for submitting the above amendment, which was received on 06/12/2023.

Research site	Principal Investigator / Local Collaborator
Royal Sussex County Hospital Brighton	Dr Duncan Bootland
St. George's Hospital London	Dr Harriet Tucker

The amendment relates solely to the addition of new site(s) and/or investigator(s) within the National Health Service (NHS) or Health and Social Care (HSC) in Northern Ireland. Site-specific assessment (SSA) for any site within the National Health Service (NHS) or Health and Social Care (HSC) in Northern Ireland will form part of the nation specific local processes for that site. Guidance on how to work with sites is provided in the IRAS help section at <https://www.myresearchproject.org.uk/help/hlpnhshscr.aspx>

On behalf of the Committee, I am pleased to confirm the extension of the favourable opinion to the new site(s) and/or investigator(s), subject to management permission being given by the relevant host organisation prior to the study starting at the site.

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.

IRAS Project ID: 300414

Please quote this number on all correspondence

Yours sincerely
PP



Jade Robinson
Approvals Administrator

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