



Blood and Transplant

Research Governance Office

500 North Bristol Park

Northway

Filton

BS34 7QH

research.office@nhsbt.nhs.uk

Dr Laura Green
NHS Blood and Transplant (Colindale)
Charcot Road
London
NW9 5BG

07 December 2022

Dear Dr Green,

Confirmation of Full Sponsorship by NHSBT

Full Project Title	A randomised controlled trial of pre-hospital whole blood transfusion versus standard care for the resuscitation of patients with life-threatening haemorrhage
Short Title	Studying Whole Blood in Frontline Trauma-SWIFT
RGO Ref	21AS0003
IRAS No.	22/SC/0072

Documents provided to Clinical Services SMT:

Document name	Document date
FRM5209 NHSBT Sponsorship Application Form	31/08/2021 (amended)
FRM5208 Risk Assessment	21/12/2021 (amended)
NHSBT Funding Award Letter	26/04/2021
MOD Funding Award Letter	22/03/2021
NHSBT Peer Review	11/03/2021

The NHSBT Clinical Services Senior Management Team (CS SMT) committee met and reviewed your application for Sponsorship on 27 September 2021 and 22nd December 2021 and you were awarded Sponsorship in Principle. Full sponsorship can only be awarded once all the conditions stated in the 'Sponsorship in Principle' letter are met. On review of evidence that you have submitted (Appendix A) we are pleased to confirm that you now have full sponsorship.

The study can commence recruitment. Please note all those concerned with the project must be compliant with GCP training.

All research projects within NHSBT must comply with the UK policy framework for health and social care research (2017). You must ensure that the NHSBT Research Governance Office is informed of any changes to the documents submitted under this application. Any changes will need to be approved by NHSBT in addition to the applicable regulatory approval requirements. Sponsorship shall remain in place until the completion date approved by an NHS REC and any regulatory requirement. However, NHSBT may withdraw Sponsorship if an investigator fails to comply with any stipulated Sponsorship conditions, or if update reports are not provided when requested.

Our Sponsorship may be withdrawn where the investigator fails to comply with our Terms & Conditions of Sponsorship.

If you have any further questions, please do not hesitate to contact us at research.office@nhsbt.nhs.uk, quoting reference 21AS0003.

Sincerely,



Oluwayomi Adegba
Head of Research Governance- Statistics and Clinical Research

cc: Dr Farrukh Shah - Medical Director for Transfusion
Dr Lise Estcourt - R&D lead for Transfusion
Joanne Lucas - NHSBT Clinical Trials Unit
Claire Rourke - NHSBT Clinical Trials Unit

Appendix A: Evidence reviewed to issue Full Sponsorship

Evidence	Date received (if applicable)
REC approval and all associated documents	10.06.2022
HRA approval	27.09.2022
CAG approval	04.04.2022
MHRA approval	02.03.2022
Evidence of funding from the Air Ambulance	
Recruiting site contracts and other appropriate contracts	
Evidence of operational support from Manufacturing	22.11.2022
Evidence of Central planning	21.11.2022
Identification of TSC members	01.11.2022
Monitoring plan	08.11.2022