

Health Research Authority (HRA)
Skipton House
80 London Road
London
SE1 6LH

28/02/2022

Dear Health Research Authority,

SWiFT: Study of Whole blood in Frontline Trauma

A multi-centre randomised controlled trial of the clinical and cost effectiveness of pre-hospital whole blood administration versus standard care (red blood cells and plasma) for major traumatic haemorrhage.

IRAS ID: 300414 **EudraCT:** 2021-006876-18 **CIs:** Dr Laura Green and Prof Jason Smith

I am pleased to enclose the Health Research Authority application for the above clinical trial. Please find below a list of all the submitted documents relating to the main trial:

- Protocol v1.0 25/02/2022
- CV (Dr Laura Green)
- Participant Information Sheets v1.0 25/02/2022
- Consent Forms v1.0 25/02/2022
- Assent Form v1.0 25/02/2022
- GP Letter v1.0 25/02/2022
- Study Poster (for relatives) v1.0 21/02/2022
- SmPC LyoPlas N-w 04/01/2021
- Sponsorship in Principle Letter
- Confirmation of Funding from NHSBT, the MOD and Air Ambulance Charities
- Confirmation of Statistical Support 28/02/2022
- Data Monitoring Committee details
- Evidence of External Peer Review
- Model Non-Commercial Agreement – TEMPLATE (unmodified)
- Organisation Information Documents x 4 (for the 4 site types*)
- Schedule of Events Cost Attribution Templates x 4 (for the 4 site types)
- Summary of PPI Feedback (Patient Information Sheets)
- Quality of Life Questionnaires – EQ5D-5L and EQ5D-Y
- Health Resource Use Questionnaire
- Cover Letter for Day 90 Questionnaires
- Non-NHS Site Assessment Forms x 10 (for the 10 Air Ambulance sites)
- Evidence of Insurance for non-NHS sites
- CVs for non-NHS site PIs

And those relating to the Qualitative Research Sub-Study ("Implementation Study"):

Blood and Transplant

Clinical Trials Unit
Long Road
Cambridge
CB2 0PT

- Implementation Study Protocol v1.0 18/02/2022
- Implementation Study Topic Guide v1.0 25/02/2022
- Participant Information Sheets v1.0 18/02/2022
- Consent Form v1.0 18/02/2022

***Site Types:**

Site type 1 – Air Ambulance

Site type 2 – Transfusion Laboratory (SoE only, as there are no treatment/service support costs)

Site type 3 – Receiving Hospital

Site type 4 – Transfusion Laboratory and Receiving Hospital

We would be most grateful for your review, and please do not hesitate to contact us if you have any queries.

Kind regards,



Dr Laura Green
Chief Investigator



Miss Emma Laing
Clinical Operations Manager