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6<sup>th</sup> January 2022

Dear Laura,

**Confirmation of Sponsorship in Principle by NHSBT**

|                           |                                                                                                                                                                |
|---------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Full Project Title</b> | A randomised controlled trial of pre-hospital whole blood transfusion versus standard care for the resuscitation of patients with life-threatening haemorrhage |
| <b>Short Title</b>        | Studying Whole Blood in Frontline Trauma-SWIFT                                                                                                                 |
| <b>R&amp;D Ref</b>        | 21AS0003                                                                                                                                                       |
| <b>IRAS No.</b>           | TBC                                                                                                                                                            |

**Documents provided to CS SMT:**

| <b>Documents provided to CS SMT:</b>              | <b>Document Date</b>            |
|---------------------------------------------------|---------------------------------|
| <b>FRM5209 NHSBT Sponsorship Application Form</b> | <b>31/08/2021<br/>(amended)</b> |
| <b>FRM5208 Risk Assessment</b>                    | <b>21/12/2021<br/>(amended)</b> |
| <b>NHSBT Funding Award Letter</b>                 | <b>26/04/2021</b>               |
| <b>MOD Funding Award Letter</b>                   | <b>22/03/2021</b>               |
| <b>NHSBT Peer Review</b>                          | <b>11/03/2021</b>               |

The NHSBT Clinical Services Senior Management Team (CS SMT) originally reviewed your application for Sponsorship in Principle in the week commencing the 27<sup>th</sup> September 2021, which was successful.

However, due to the study being re-categorised as a Clinical Trial of an Investigational Medicinal Product, new documentation was produced. The amended documents were sent to CS SMT on 22<sup>nd</sup> December 2021. No objections were received. Therefore, the Sponsorship in Principle decision is still in place.

Please be advised that NHSBT's agreement to Sponsor this study in principle does not provide approval for the study to start. The study cannot commence until the following conditions have been met:

- The R&D Office have received the full document set, including the study Protocol, in enough time for review prior to HRA submission.
- REC/Health Research Authority/Confidentiality Advisory Group approval is sought and received and no subsequent operational issues are identified.

- MHRA approval is sought and received.
- Evidence of funding from the Air Ambulance Charities has been confirmed.
- Appropriate contracts are put in place.
- Evidence of operation support from Manufacturing has been received.
- Confirmation received from central planning that the use of O negative blood is not an issue.
- Identification of TSC members has taken place.

Please ensure that the NHSBT R&D Office receives a copy of all approvals obtained. NHSBT R&D Office will request a complete set of approved documents.

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 R&D 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 or any regulatory requirements. 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.

Full Sponsorship will be issued when the conditions outlined in this letter have been met. Please liaise with the R&D Office directly when documents, including study protocol, are ready and they will advise you on how Sponsorship in Principle is transferred to full Sponsorship. 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](mailto:research.office@nhsbt.nhs.uk), quoting reference 21AS0003.

Yours sincerely,



Oluwayomi Adegaju, National Research Manager, NHSBT

Cc: Emma Laing, CTU, NHSBT  
Joanne Lucas, CTU, NHSBT