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27 September 2022

Dear Dr Green

**HRA and Health and Care
Research Wales (HCRW)
Approval Letter**

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
IRAS project ID:	300414
EudraCT number:	2021-006876-18
Protocol number:	v1.0
REC reference:	22/SC/0072
Sponsor	NHS Blood and Transplant

I am pleased to confirm that [**HRA and Health and Care Research Wales \(HCRW\) Approval**](#) has been given for the above referenced study, on the basis described in the application form, protocol, supporting documentation and any clarifications received. You should not expect to receive anything further relating to this application.

Please now work with participating NHS organisations to confirm capacity and capability, in line with the instructions provided in the “Information to support study set up” section towards the end of this letter.

How should I work with participating NHS/HSC organisations in Northern Ireland and Scotland?

HRA and HCRW Approval does not apply to NHS/HSC organisations within Northern Ireland and Scotland.

If you indicated in your IRAS form that you do have participating organisations in either of these devolved administrations, the final document set and the study wide governance report (including this letter) have been sent to the coordinating centre of each participating nation. The relevant national coordinating function/s will contact you as appropriate.

Please see [IRAS Help](#) for information on working with NHS/HSC organisations in Northern Ireland and Scotland.

How should I work with participating non-NHS organisations?

HRA and HCRW Approval does not apply to non-NHS organisations. You should work with your non-NHS organisations to [obtain local agreement](#) in accordance with their procedures.

What are my notification responsibilities during the study?

The standard conditions document “[After Ethical Review – guidance for sponsors and investigators](#)”, issued with your REC favourable opinion, gives detailed guidance on reporting expectations for studies, including:

- Registration of research
- Notifying amendments
- Notifying the end of the study

The [HRA website](#) also provides guidance on these topics, and is updated in the light of changes in reporting expectations or procedures.

Who should I contact for further information?

Please do not hesitate to contact me for assistance with this application. My contact details are below.

Your IRAS project ID is **300414**. Please quote this on all correspondence.

Yours sincerely,
Hayleigh Morris

Email: approvals@hra.nhs.uk HCRW.approvals@wales.nhs.uk

Copy to: *Ms Joanne Lucas, NHS Blood and Transplant*

List of Documents

The final document set assessed and approved by HRA and HCRW Approval is listed below.

Document	Version	Date
Confirmation of any other Regulatory Approvals (e.g. CAG) and all correspondence [CAG Approval]		26 September 2022
Confirmation of Clinical Trial Authorisation from MHRA and relevant correspondence [SWiFT CTA Notification Acceptance]		02 March 2022
Contract/Study Agreement template [SWiFT - template mNCA (unmodified)]	N/A	25 February 2022
Covering letter on headed paper [SWiFT - HRA Application Cover Letter]	N/A	28 February 2022
Details of any Data Monitoring Committee [SWiFT Trial - Data Monitoring Committee]	N/A	07 February 2022
GP/consultant information sheets or letters [SWiFT - GP Letter]	1.1	03 May 2022
IRAS Application Form [IRAS_Form_28022022]		28 February 2022
Letter from funder [Whole Blood Trial - NHSBT Award Letter]	N/A	21 July 2021
Letter from sponsor [SWiFT - Sponsorship in Principle Letter]	N/A	06 January 2022
Letter from statistician [SWiFT - Letter of Statistical Support]	N/A	28 February 2022
Non-validated questionnaire [Health Resource Use Questionnaire]	v1.0	25 February 2022
Organisation Information Document [SITE TYPE 2 - TRANSFUSION LABORATORY]		17 March 2022
Organisation Information Document [SITE TYPE 3 - RECEIVING HOSPITAL]		17 March 2022
Organisation Information Document [SITE TYPE 4 - TRANSFUSION LABORATORY AND RECEIVING HOSPITAL]		17 March 2022
Other [SWiFT - Summary of PPI Feedback]	N/A	22 February 2022
Other [SWiFT - Poster for Relatives]	v1.0	21 February 2022
Other [Whole Blood Trial - MOD Award Letter]	N/A	22 March 2021
Other [SWiFT - Evidence of Air Ambulance Charity Funding (Finance Agreement)]	N/A	22 December 2021
Other [SWiFT Implementation Study Protocol]	v1.0	18 February 2022
Other [SWiFT Implementation Study Topic Guide]	v1.0	25 February 2022
Other [SWiFT - Cover Letter for Day 90 Questionnaires]	v1.0	25 February 2022
Other [SWiFT Trial Protocol_v1.1_03.05.2022 TC]	1.1	03 May 2022
Other [SWiFT - Poster for Relatives]	1.1	03 May 2022
Other [SWiFT Implementation Study_Consent Form]	1.1	22 April 2022
Other [Evidence of Insurance EHAAT]	1.0	03 May 2022
Other [SWiFT_GP Letter_EQ5D5L referral_v1.0_2022 05 03]	1.0	03 May 2022
Other [Research CV - Scott Beattie]	1.0	20 January 2022
Other [SWiFT_ Response letter to REC and CAG_v1.0_2022 05 04]	1.0	04 May 2022
Other [SWiFT Response letter to REC and CAG - table]	1.0	04 May 2022
Other [1 SWiFT Patient Information Sheet_v1.1_2022 05 03 TC]	1.1	03 May 2022
Other [2 SWiFT Patient Consent Form_v1.1_2022 05 03 TC]	1.1	03 May 2022
Other [3 SWiFT Legal Representative Information Sheet_v1.1_2022 05 03 TC]	1.1	03 May 2022
Other [4 SWiFT Legal Representative Consent Form_v1.1_2022 05 03 TC]	1.1	03 May 2022
Other [5 SWiFT Parent+Guardian Information Sheet_v1.1_2022 05 03 TC]	1.1	03 May 2022

Other [6 SWiFT Parent+Guardian Consent Form_v1.1_2022 05 03 TC]	1.1	03 May 2022
Other [Grazia_Antonacci_CV_03_2022]	1.0	01 March 2022
Other [SWiFT - privacy notice for website_v1.1_2022 05 03 TC]	1.1	03 May 2022
Other [SWiFT Implementation Study_Consent Form_v1.1_2022_04_22_TC]	1.1	22 April 2022
Other [SWiFT_GP Letter_EQ5D5L referral_v1.0_2022 05 03]	1.0	03 May 2022
Other [DSAA Public liability]		
Other [EHAAT PL Certificate]		
Other [GNAAS - PL Certificate]		
Other [LAA - PL Certificate]		
Other [SWiFT_ Response letter to REC and CAG]	1.0	15 August 2022
Other [GWAA Public Liability Insurance]		
Other [AAKSS - PL Certificate]		
Other [Response to FOWC]		
Participant consent form [Professional Legal Representative Consent Form]	v1.0	25 February 2022
Participant consent form [Assent Form]	v1.0	25 February 2022
Participant consent form [Parent/Guardian Consent Form]	1.1	03 May 2022
Participant consent form [Legal Representative Consent Form]	1.1	03 May 2022
Participant consent form [Patient Consent Form]	1.1	03 May 2022
Participant information sheet (PIS) [Patient Information Sheet]	1.1	03 May 2022
Participant information sheet (PIS) [Legal Representative Information Sheet]	1.1	03 May 2022
Participant information sheet (PIS) [Patient Information Sheet (aged 6-10 years)]	1.1	03 May 2022
Participant information sheet (PIS) [Parent/Guardian Information Sheet]	1.1	03 May 2022
Participant information sheet (PIS) [Patient Information Sheet (aged 11-15 years)]	1.1	03 May 2022
Participant information sheet (PIS) [SWiFT Implementation Study_PIS - HCP Focus Group]	1.2 (Clean)	26 August 2022
Participant information sheet (PIS) [SWiFT Implementation Study_PIS - HCP Focus Group]	1.2 (TC)	26 August 2022
Participant information sheet (PIS) [SWiFT Implementation Study_PIS - HCP Focus Groups 2-6]	1.2 (Clean)	26 August 2022
Participant information sheet (PIS) [SWiFT Implementation Study_PIS - HCP Focus Groups 2-6]	1.2 (TC)	26 August 2022
Participant information sheet (PIS) [SWiFT Implementation Study_PIS - HCP Interviews]	1.2 (Clean)	26 August 2022
Participant information sheet (PIS) [SWiFT Implementation Study_PIS - HCP Interviews]	1.2 (TC)	26 August 2022
Participant information sheet (PIS) [SWiFT Implementation Study_PIS - Patient Donor Focus Group]	1.2 (Clean)	26 August 2022
Participant information sheet (PIS) [SWiFT Implementation Study_PIS - Patient Donor Focus Group]	1.2 (TC)	26 August 2022
Referee's report or other scientific critique report [Evidence of External Peer Review]		
Research protocol or project proposal [SWiFT Trial Protocol]	1.1	03 May 2022
Schedule of Events or SoECAT [SITE TYPE 2 - TRANSFUSION LABORATORY - SoE]	N/A	21 February 2022
Schedule of Events or SoECAT [SITE TYPE 3 - RECEIVING HOSPITAL - SoECAT]	N/A	18 February 2022
Schedule of Events or SoECAT [SITE TYPE 4 - TRANSFUSION	N/A	18 February 2022

LABORATORY AND RECEIVING HOSPITAL - SoECAT]		
Summary CV for Chief Investigator (CI) [Dr Laura Green - CV]		02 August 2021
Summary of product characteristics (SmPC) [SmPC - LyoPlas]	N/A	04 January 2021
Validated questionnaire [EQ-5D-5L (self-complete)]		
Validated questionnaire [EQ-5D-5L (interviewer administrated)]		
Validated questionnaire [EQ-5D-Y (interviewer administrated)]		
Validated questionnaire [EQ-5D-Y (self-complete)]		

Information to support study set up

The below provides all parties with information to support the arranging and confirming of capacity and capability with participating NHS organisations in England and Wales. This is intended to be an accurate reflection of the study at the time of issue of this letter.

Types of participating NHS organisation	Expectations related to confirmation of capacity and capability	Agreement to be used	Funding arrangements	Oversight expectations	HR Good Practice Resource Pack expectations
Site Type2(Transfusion Laboratory) Site Type 3(Receiving Hospital) Site Type 4(Transfusion Laboratory and Receiving Hospital)	Research activities should not commence at participating NHS organisations in England or Wales prior to their formal confirmation of capacity and capability to deliver the study.	An Organisation Information Document has been submitted and the sponsor is intending to use a separate site agreement. The agreement is unmodified.	External funding has been secured from NHS Blood and Transplant, Air Ambulance Charities and the Ministry of Defence. Funding will be provided to site as detailed in the OID and agreement.	Principal Investigators (PIs) are expected.	Where arrangements are not already in place, research staff not employed by the NHS host organisation undertaking any of the research activities listed in the research application would be expected to obtain an honorary research contract from one NHS organisation (if university employed), followed by Letters of Access for subsequent organisations. This would be on the basis of a Research Passport (if university employed) or an NHS to NHS confirmation of pre-engagement checks letter (if NHS employed). These should confirm enhanced DBS checks, including appropriate barred list checks, and occupational health clearance.

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Other information to aid study set-up and delivery

<i>This details any other information that may be helpful to sponsors and participating NHS organisations in England and Wales in study set-up.</i>
The applicant has indicated that they intend to apply for inclusion on the NIHR CRN Portfolio. Site Type 1 (Air Ambulance) & Interview/Focus Groups: Some activity will take place outside the NHS. HRA & HCRW Approval does not cover activity outside the NHS. Before undertaking activity outside the NHS the research team must follow the procedures and governance arrangements of responsible organisations.