



Health Research Authority

South Central - Oxford C Research Ethics Committee

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**Please note: This is an
acknowledgement letter from
the REC only and does not
allow you to start your study
at NHS sites in England until
you receive HRA Approval**

12 September 2022

Dr Laura Green
Principal Investigator in Transfusion Research and Innovation (NHS Blood and Transplant),
Consultant Haematologist in Haemostasis and Transfusion Medicine (Bart's Health NHS Trust)
NHS Blood and Transplant & Bart's Health NHS Trust
NHS Blood and Transplant Colindale
Charcot Road
London
NW9 5BG

Dear Dr Green

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
IRAS project ID:	300414

Thank you for your letter of 08 September 2022. I can confirm the REC has received the documents listed below and that these comply with the approval conditions detailed in our letter dated 10 June 2022.

Documents Received

The documents received were as follows:

Document	Version	Date
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Other [AAKSS - PL Certificate]		
Other [Response to FOWC]		
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

Approved Documents

The final list of approved documentation for the study is therefore as follows:

<i>Document</i>	<i>Version</i>	<i>Date</i>
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-NHS/HSC Site Assessment Form [AAKSS (IN23)]	N/A	23 February 2022
Non-NHS/HSC Site Assessment Form [DSAA (IN27)]	N/A	28 February 2022
Non-NHS/HSC Site Assessment Form [GWAAC (IN29)]	N/A	24 February 2022
Non-NHS/HSC Site Assessment Form [HIOWAA (IN30)]	N/A	26 February 2022
Non-NHS/HSC Site Assessment Form [LAA (IN31)]	N/A	28 February 2022
Non-NHS/HSC Site Assessment Form [Magpas (IN24)]	N/A	24 February 2022
Non-NHS/HSC Site Assessment Form [NWAA (IN22)]	N/A	28 February 2022
Non-NHS/HSC Site Assessment Form [TVAA (IN25)]	N/A	23 February 2022
Non-NHS/HSC Site Assessment Form [EHAAT (IN28)]	N/A	24 February 2022
Non-NHS/HSC Site Assessment Form [GNAAS (IN37)]	N/A	23 February 2022
Non-validated questionnaire [Health Resource Use Questionnaire]	v1.0	25 February 2022
Other [SWiFT - Summary of PPI Feedback]	N/A	22 February 2022
Other [CV for PI of non-NHS Site - AAKSS (IN23)]	N/A	23 February 2022

Other [CV for PI of non-NHS Site - DSAA (IN27)]	N/A	24 February 2022
Other [CV for PI of non-NHS Site - EHAAT (IN28)]	N/A	24 February 2022
Other [CV for PI of non-NHS Site - GNAAS (IN37)]	N/A	13 February 2022
Other [CV for PI of non-NHS Site - GWAAC (IN29)]	N/A	24 February 2022
Other [CV for PI of non-NHS Site - HIOWAA (IN30)]	N/A	26 February 2022
Other [CV for PI of non-NHS Site - LAA (IN31)]	N/A	31 December 2021
Other [CV for PI of non-NHS Site - Magpas (IN24)]	N/A	24 February 2022
Other [CV for PI of non-NHS Site - NWAA (IN22)]	N/A	28 February 2022
Other [CV for PI of non-NHS Site - TVAA (IN25)]	N/A	23 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 [Evidence of Insurance - AAKSS (IN23)]	N/A	28 February 2022
Other [Evidence of Insurance - DSAA (IN27)]	N/A	28 February 2022
Other [Evidence of Insurance - EHAAT (IN28)]	N/A	28 February 2022
Other [Evidence of Insurance - GWAAC (IN29)]	N/A	28 February 2022
Other [Evidence of Insurance - GNAAS (IN37)]	N/A	25 February 2022
Other [Evidence of Insurance - HIOWAA (IN30)]	N/A	25 February 2022
Other [Evidence of Insurance - LAA (IN31)]	N/A	28 February 2022
Other [Evidence of Insurance - Magpas (IN24)]	N/A	25 February 2022
Other [Evidence of Insurance - NWAA (IN22)]	N/A	25 February 2022
Other [Evidence of Insurance - TVAA (IN25)]	N/A	25 February 2022
Other [SWiFT - Cover Letter for Day 90 Questionnaires]	v1.0	25 February 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

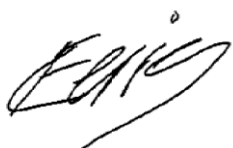
Other [Grazia_Antonacci_CV_03_2022]	1.0	01 March 2022
Other [SWiFT - privacy notice for website_v1.1_2022 05 03 TC]	1.1	03 May 2022
Other [SWiFT Implementation Study_Consent Form_v1.1_2022_04_22_TC]	1.1	22 April 2022
Other [SWiFT Trial Protocol_v1.1_03.05.2022 TC]	1.1	03 May 2022
Other [SWiFT_GP Letter_EQ5D5L 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
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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

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)]		

You should ensure that the sponsor has a copy of the final documentation for the study. It is the sponsor's responsibility to ensure that the documentation is made available to R&D offices at all participating sites.

IRAS Project ID: 300414	Please quote this number on all correspondence
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Yours sincerely



Charlotte Ferris
Approvals Officer

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Copy to: Ms Joanne Lucas, NHS Blood and Transplant