



Health Research Authority

South Central - Oxford C Research Ethics Committee

Health Research Authority (Bristol)
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Telephone: 0207 104 8241

Please note: This is the favourable opinion of the REC only and does not allow you to start your study at NHS sites in England until you receive HRA Approval

10 June 2022

Dr Laura Green

Principal Investigator in Transfusion Research and Innovation (NHS Blood and Transplant),
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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 11 May 2022, responding to the Research Ethics Committee's (REC) request for further information on the above research and submitting revised documentation.

The further information has been considered on behalf of the Committee by the Chair, Dr Lee Potiphar, along with Committee Member – Dr Pamela Ross.

Confirmation of Ethical Opinion

On behalf of the Committee, I am pleased to confirm a favourable ethical opinion for the above research on the basis described in the application form, protocol and supporting documentation as revised, subject to the conditions specified below.

Good Practice Principles and Responsibilities

The [UK Policy Framework for Health and Social Care Research](#) sets out principles of good practice in the management and conduct of health and social care research. It also outlines the responsibilities of individuals and organisations, including those related to the four elements of [research transparency](#):

1. [registering research studies](#)
2. [reporting results](#)
3. [informing participants](#)
4. [sharing study data and tissue](#)

Conditions of the Favourable Opinion

The REC favourable opinion is subject to the following conditions being met prior to the start of the study.

Number	Action Required
1	Submission of evidence of insurance for the Non-NHS Air Ambulance sites is pending: a) IN26 (Air Ambulance Charity Kent Surrey Sussex (AAKSS)) – a print out of an email has been supplied. Please submit evidence of the insurance e.g. certificate. b) IN27 (Dorset and Somerset Air Ambulance (DSAA)), IN29 (Great Western Air Ambulance Charity (GWAAC)), IN31 (London's Air Ambulance (LAA)) and IN32 (The Great North Air Ambulance Service (GNAAS)) – printouts of emails have been supplied suggesting that NHS indemnity applies. Even though NHS indemnity could apply for the staff undertaking the research, the site itself should have insurance arrangements in place (e.g. public liability) as my understanding is that these sites are taking on responsibility for activities taking place. Evidence of this insurance should be submitted. c) IN28 (Essex & Herts Air Ambulance (EHAAT)) – the full policy document has been submitted. Please provide the insurance certificate with the name of the organisation specified. NOTE: If it transpires that any of the Air Ambulance sites are considered NHS sites rather than non-NHS, the non-NHS SSA will be withdrawn and it would be expected that an OID, model agreement and SOE/SOECAT is submitted for this site for the purposes of HRA Approval.

You should notify the REC once all conditions have been met (except for site approvals from host organisations) and provide copies of any revised documentation with updated version numbers. Revised documents should be submitted to the REC electronically from IRAS. The REC will acknowledge receipt and provide a final list of the approved documentation for the study, which you can make available to host organisations to facilitate their permission for the study. Failure to provide the final versions to the REC may cause delay in obtaining permissions.

Confirmation of Capacity and Capability (in England, Northern Ireland and Wales) or NHS management permission (in Scotland) should be sought from all NHS organisations involved in the study in accordance with NHS research governance arrangements. Each NHS organisation must confirm through the signing of agreements and/or other documents that it has given permission for the research to proceed (except where explicitly specified otherwise).

Guidance on applying for HRA and HCRW Approval (England and Wales)/ NHS permission for research is available in the Integrated Research Application System.

For non-NHS sites, site management permission should be obtained in accordance with the procedures of the relevant host organisation.

Sponsors are not required to notify the Committee of management permissions from host organisations

Registration of Clinical Trials

All research should be registered in a publicly accessible database and we expect all researchers, research sponsors and others to meet this fundamental best practice standard.

It is a condition of the REC favourable opinion that **all clinical trials are registered** on a publicly accessible database within six weeks of recruiting the first research participant. For this purpose, 'clinical trials' are defined as:

- clinical trial of an investigational medicinal product
- clinical investigation or other study of a medical device
- combined trial of an investigational medicinal product and an investigational medical device
- other clinical trial to study a novel intervention or randomised clinical trial to compare interventions in clinical practice.

Failure to register a clinical trial is a breach of these approval conditions, unless a deferral has been agreed by the HRA (for more information on registration and requesting a deferral see: [Research registration and research project identifiers](#)).

If you have not already included registration details in your IRAS application form you should notify the REC of the registration details as soon as possible.

CTIMPs submitted for combined review via IRAS will be registered automatically with the [ISRCTN Registry](#). You do not need to notify the REC of the registration details. The lawful basis

for processing your personal data for this purpose is official authority under the NHS Care Act 2014 (for further information please see our [privacy notice](#)).

Publication of Your Research Summary

We will publish your research summary for the above study on the research summaries section of our website, together with your contact details, no earlier than three months from the date of this favourable opinion letter.

Should you wish to provide a substitute contact point, make a request to defer, or require further information, please visit:

<https://www.hra.nhs.uk/planning-and-improving-research/application-summaries/research-summaries/>

N.B. If your study is related to COVID-19 we will aim to publish your research summary within 3 days rather than three months.

During this public health emergency, it is vital that everyone can promptly identify all relevant research related to COVID-19 that is taking place globally. If you haven't already done so, please register your study on a public registry as soon as possible and provide the REC with the registration detail, which will be posted alongside other information relating to your project. We are also asking sponsors not to request deferral of publication of research summary for any projects relating to COVID-19. In addition, to facilitate finding and extracting studies related to COVID-19 from public databases, please enter the WHO official acronym for the coronavirus disease (COVID-19) in the full title of your study. Approved COVID-19 studies can be found at: <https://www.hra.nhs.uk/covid-19-research/approved-covid-19-research/>

Clinical trial authorisation must be obtained from the Medicines and Healthcare products Regulatory Agency (MHRA).

It is the responsibility of the sponsor to ensure that all the conditions are complied with before the start of the study or its initiation at a particular site (as applicable).

After ethical review: Reporting requirements

The attached document "After ethical review – guidance for researchers" gives detailed guidance on reporting requirements for studies with a favourable opinion, including:

- Notifying substantial amendments
- Adding new sites and investigators
- Notification of serious breaches of the protocol
- Progress and safety reports
- Notifying the end of the study, including early termination of the study
- Final report
- Reporting results

The latest guidance on these topics can be found at <https://www.hra.nhs.uk/approvals-amendments/managing-your-approval/>.

Ethical Review of Research Sites

NHS/HSC sites

The favourable opinion applies to all NHS/HSC sites taking part in the study, subject to confirmation of Capacity and Capability (in England, Northern Ireland and Wales) or management permission (in Scotland) being obtained from the NHS/HSC R&D office prior to the start of the study (see "Conditions of the favourable opinion" below).

Non-NHS/HSC sites

I am pleased to confirm that the favourable opinion applies to any non-NHS/HSC sites listed in the application, subject to site management permission being obtained prior to the start of the study at the site.

Approved Documents

The final list of documents reviewed and approved by the Committee is 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 [HLOWAA (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_PIS - HCP Focus Group 1]	1.1	22 April 2022
Other [SWiFT Implementation Study_PIS - HCP Focus Groups 2-6]	1.1	22 April 2022
Other [SWiFT Implementation Study_PIS - Patient Donor Focus Group]	1.1	22 April 2022
Other [SWiFT Implementation Study_Consent Form]	1.1	22 April 2022
Other [Evidence of Insurance EHAAT]	1.0	03 May 2022
Other [Evidence of Insurance KSS]	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]	1.1	03 May 2022

TC]		
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 Implementation Study_PIS - HCP Focus Group 1_v1.1_2022_04_22_TC]	1.1	22 April 2022
Other [SWiFT Implementation Study_PIS - HCP Focus Groups 2-6_v1.1_2022_04_22_TC]	1.1	22 April 2022
Other [SWiFT Implementation Study_PIS - HCP Interviews_v1.1_2022_04_22_TC]	1.1	22 April 2022
Other [SWiFT Implementation Study_PIS - Patient Donor Focus Group_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
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
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)]		

Statement of Compliance

This Committee is recognised by the United Kingdom Ethics Committee Authority under the Medicines for Human Use (Clinical Trials) Regulations 2004, and is authorised to carry out the ethical review of clinical trials of investigational medicinal products.

The Committee is fully compliant with the Regulations as they relate to ethics committees and the conditions and principles of good clinical practice.

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

User Feedback

The Health Research Authority is continually striving to provide a high quality service to all applicants and sponsors. You are invited to give your view of the service you have received and the application procedure. If you wish to make your views known please use the feedback form available on the HRA website:

<http://www.hra.nhs.uk/about-the-hra/governance/quality-assurance/>

HRA Learning

We are pleased to welcome researchers and research staff to our HRA Learning Events and online learning opportunities– see details at:

<https://www.hra.nhs.uk/planning-and-improving-research/learning/>

IRAS project ID: 300414 Please quote this number on all correspondence
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With the Committee's best wishes for the success of this project.

Yours sincerely



PP
Dr Lee Potiphar
Chair

Email: oxfordc.rec@hra.nhs.uk

Copy to: Ms Joanne Lucas, NHS Blood and Transplant
 Confidentiality Advice Team