



Health Research Authority

2 Redman Place
Stratford
London
E20 1JQ

Tel: 020 7104 8100
Email: cag@hra.nhs.uk

26 September 2022

Ms Yomi Adegbaju
NHS Blood and Transplant
500, North Bristol Park
Filton
Bristol
BS34 7QH

Dear Ms Adegbaju

Application 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
CAG reference:	22/CAG/0050
IRAS project ID:	300414
REC reference:	22/SC/0072

Thank you for submitting a **research** application under Regulation 5 of the Health Service (Control of Patient Information) Regulations 2002 ('section 251 support') to process confidential patient information without consent.

Supported applications allow the controller(s) of the relevant data sources, if they wish, to provide specified information to the applicant for the purposes of the relevant activity without being in breach of the common law duty of confidence. Support provides a lawful basis to allow the information to be processed by the relevant parties for the specified purposes without incurring a breach of the common law duty of confidence only. Applicants must ensure the activity remains fully compliant with all other relevant legislation.

The role of the Confidentiality Advisory Group (CAG) is to review applications submitted under these Regulations and to provide advice to the Health Research Authority on whether application activity should be supported, and if so, any relevant conditions. This application was considered at the CAG meeting held on 24 March 2022.

This outcome should be read in conjunction with the provisional support letter dated 04 April 2022.

Health Research Authority decision

The Health Research Authority, having considered the advice from the Confidentiality Advisory Group as set out below, has determined the following:

The application, to allow the research team at participating NHS trusts to access patient records to check for evidence of existing dissent to use of their data in research, the disclosure of confidential patient information from the NHS trusts to NHSBT Clinical Trials Unit and the onward disclosure to TARN and ICNARC for data linkage, and the return of a linked, pseudonymised dataset to NHSBT, is conditionally supported, subject to compliance with the standard and specific conditions of support.

Please note that the legal basis to allow access to the specified confidential patient information without consent is now in effect.

Context

Purpose of application

This application from NHS Blood and Transplant set out the purpose of medical research that seeks to determine whether pre-hospital leukocyte-depleted whole blood transfusion is better than standard care in reducing the proportion of participants who experience death or massive transfusion.

More than 5,400 people die every year in the UK as a result of major trauma. Uncontrolled bleeding accounts for a large proportion of these deaths, with approximately 20% occurring in the first 24 hours and 40% occurring within the first 30 days. The overall cost to the NHS for managing major trauma is estimated to be £150 million per annum and blood transfusion makes up around 12% of this cost. Blood transfusion is a life-saving treatment in the management of bleeds and is typically delivered through different blood components. These components, red blood cells, plasma and platelets, are derived from whole blood donation and stored in separate bags. Carrying several different blood products can cause problems, such as additional weight in kit bags, and transfusing multiple blood products at scene may delay transport to hospital. Most UK Air Ambulance Services carry red blood cells and plasma to transfuse pre-hospital. However, a pre-hospital transfusion strategy has not been established and practice varies across the country. This trial aims to investigate if carrying and transfusing two units of whole blood instead of four units (two red blood cells and two plasma) leads to better outcomes for patients and reduces costs.

Randomised boxes containing either 2 units of whole blood or 2 units of red blood cells and 2 units of plasma, will be prepared in advance by the Transfusion Laboratory Teams and supplied to the participating Air Ambulance Services. If they attend a patient who has suffered major trauma and requires blood transfusion, the team will open the trial intervention box and administer the contents to the patient, in accordance with standard local blood transfusion protocols. The time that the box was opened will be recorded and referred to as the randomisation time for the purposes of follow-up data collection. The Air Ambulance team will notify the team at the receiving hospital if the patient has been enrolled into the SWiFT trial and provide the relevant randomisation number. Patients will be followed up for up to 90 days post-randomisation. Additional data, which is routinely collected by the Trauma Audit and Research Network (TARN) and the Intensive Care National Audit and Research Centre (ICNARC), will also be obtained. Consent cannot be sought at the time of recruitment to the trial, as the patients will not have capacity. Patients will be enrolled under the emergency provisions of the Clinical Trial Regulations and consent sought, where possible, once capacity is regained. Once informed consent has been obtained, confidential patient information will be securely

provided to NHSBT CTU by the Research Team. This will allow for linkage to the TARN and ICNARC datasets. Support under Regulation 5 is sought to include patients who could not be consented, due to death or to being discharged prior to consent being sought.

A recommendation for class 4 and 6 support was requested to cover access to the relevant unconsented activities as described in the application.

Confidential patient information requested

The following sets out a summary of the specified cohort, listed data sources and key identifiers. Where applicable, full datasets and data flows are provided in the application form and relevant supporting documentation as this letter represents only a summary of the full detail.

Cohort	Patients aged 0 years and above who are attended by a participating Air Ambulance Service (AAS) clinical team and required pre-hospital blood transfusion to treat major traumatic haemorrhage. The applicants anticipate that 848 patients will be recruited.
Data sources	1. Intensive Care National Audit and Research Centre (ICNARC). 2. Trauma Audit and Research Network (TARN)
Identifiers required for linkage purposes	1. NHS number 2. Date of birth
Identifiers required for analysis purposes	1. Date of death 2. Gender

Confidentiality Advisory Group advice

This letter summarises the outstanding elements set out in the provisional support letter, and the applicant response. The applicant response was considered by a sub-committee of the CAG.

- 1. Confirm that patients would be approached with information about the study when they had capacity to consent. For patients who lacked capacity, their legal representative needed to be approached as soon as possible.**

The applicants confirmed that patients will be approached when they regain capacity to consent. Until this time, consent from a legal representative will be sought as soon as possible. The CAG reviewed this information and raised no further queries.

- 2. The patient notification materials need to explain clearly that patients could opt-out. Telephone, postal and email contacts also need to be provided.**

A revised privacy notice and study poster was provided, which had been revised in line with the above. The CAG reviewed the revised documents and raised no further queries.

3. **The sentence about the Confidentiality Advisory Group in the Privacy Notice needs to be revised to state that “The Confidentiality Advisory Group have recommended that support under Regulation 5 of the Health Service (Control of Patient Information) Regulations 2002 (‘section 251 support’) is given for the processing of confidential patient information...”**

A revised privacy notice was provided, which had been revised in line with the above. The CAG reviewed the revised document and raised no further queries.

Confidentiality Advisory Group advice conclusion

The CAG agreed that the minimum criteria under the Regulations appeared to have been met, and therefore advised recommending support to the Health Research Authority, subject to compliance with the specific and standard conditions of support as set out below.

Specific conditions of support

1. Favourable opinion from a Research Ethics Committee. **Confirmed 12 September 2022.**
2. Confirmation provided from the IG Delivery Team at NHS Digital to the CAG that the relevant Data Security and Protection Toolkit (DSPT) submission(s) has achieved the ‘Standards Met’ threshold. See section below titled ‘security assurance requirements’ for further information. **Confirmed:**

The NHS Digital **2020/21** DSPT reviews for **NHS Blood and Transplant, ICNARC and TARN** were confirmed as ‘Standards Met’ on the NHS Digital DSPT Tracker (checked 27 May 2022).

As the above conditions have been accepted and met, this letter provides confirmation of final support. I will arrange for the register of approved applications on the HRA website to be updated with this information

Application maintenance

Annual review

Please note that this legal support is subject to submission of an annual review report, for the duration of support, to show that the minimal amount of patient information is being processed and support is still necessary, how you have met the conditions or report plans, any public benefits that have arisen and action towards meeting them. It is also your responsibility to submit this report every 12 months for the entire duration that confidential patient information is being processed without consent.

The next annual review should be provided no later than **26 September 2023** and preferably 4 weeks before this date. Reminders are not issued so please ensure this is provided annually to avoid jeopardising the status of the support. Submission of an annual review in line with this schedule remains necessary even where there has been a delay to the commencement of the supported activity, or a halt in data processing.

Please ensure you review the HRA website to ensure you are completing the most up to date 'section 251' annual review form as these may change.

For an annual review to be valid, there must also be evidence that the relevant DSPT submission(s) for organisations processing confidential patient information without consent are in place and have been reviewed by NHS Digital. Please plan to contact NHS Digital in advance of the CAG annual review submission date to check they have reviewed the relevant DSPTs and have confirmed these are satisfactory.

Register of Approved Applications

All supported applications to process confidential patient information without consent are listed in the published 'Register of Approved Applications'. It is a statutory requirement for the Register to be published and it is available on the CAG section of the Health Research Authority website. It contains applicant contact details, a summary of the research and other pertinent points.

This Register is used by controllers to check whether support is in place.

Changes to the application

The application and relevant documents set out the scope of the support which is in place for the application activity and any relevant restrictions around this.

Any amendments which are made to the scope of this support, including but not limited to, purpose, data flows, data sources, items of confidential patient information and processors, require submission of a formal amendment to the application. Changes to processors will require evidence of satisfactory DSPT submission. The amendment form can be found in the Confidentiality Advisory Group pages on the Health Research Authority website.

Support for any submitted amendment would not come into effect until a positive outcome letter has been issued.

Changes to the controller

Amendments which involve a change to the named controller for the application activity require the submission of a new and signed CAG application form and supporting documentation to support the application amendment. This is necessary to ensure that the application held on file appropriately reflects the organisation taking responsibility for the manner and purpose of data processing within the application, and that the legal support in place is related to the correct legal entity.

Applicants are advised to make contact with the Confidentiality Advice Team to discuss a change in controllership for an existing application in sufficient time ahead of the transfer of project responsibility to discuss the submission process timings.

Further information and relevant forms to amend the support is available on the HRA website.

Reviewed documents

The documents reviewed at the meeting are as follows.

<i>Document</i>	<i>Version</i>	<i>Date</i>
CAG application from (signed/authorised) [SWiFT - CAG Form SUBMITTED 04.03.2022]		04 March 2022
Data Protection Registration [Data Protection Registration - NHS Blood and Transplant]		
Other [List of Participating Sites]		
Other [SWiFT Data Linkage - responses from PPI group members]		
Other [SWiFT Data Flowchart AMENDED]		
Patient Information Materials [SWiFT Study Poster_v1.1_2022 05 03]	1.1	03 May 2022
Patient Information Materials [SWiFT - privacy notice for website_v1.1_2022 05 03 Clean]	1.1	03 May 2022
Patient Information Materials [SWiFT - privacy notice for website_v1.1_2022 05 03 TC]	1.1	03 May 2022
SWiFT Response letter to REC and CAG - table		
SWiFT_ Response letter to REC and CAG_v1.0_2022 05 04	1.0	04 May 2022
Written recommendation from Caldicott Guardian (or equivalent) of applicant's organisation [SWiFT CAG Support Letter - Caldicott Guardian - 03.03.2022]		03 March 2022
Patient Information Materials SWiFT Patient Information Sheet_v1.1_2022 05 03 Clean	1.1	03 May 2022
Patient Information Materials SWiFT Patient Information Sheet_v1.1_2022 05 03 TC	1.1	03 May 2022
Patient Information Materials SWiFT Patient Consent Form_v1.1_2022 05 03 Clean	1.1	03 May 2022
Patient Information Materials SWiFT Patient Consent Form_v1.1_2022 05 03 TC	1.1	03 May 2022
Patient Information Materials SWiFT Legal Representative Information Sheet_v1.1_2022 05 03 Clean	1.1	03 May 2022
Patient Information Materials SWiFT Legal Representative Information Sheet_v1.1_2022 05 03 TC	1.1	03 May 2022
Patient Information Materials SWiFT Legal Representative Consent Form_v1.1_2022 05 03 Clean	1.1	03 May 2022
Patient Information Materials SWiFT Legal Representative Consent Form_v1.1_2022 05 03 TC	1.1	03 May 2022
Patient Information Materials SWiFT Parent+Guardian Information Sheet_v1.1_2022 05 03 Clean	1.1	03 May 2022
Patient Information Materials SWiFT Parent+Guardian Information Sheet_v1.1_2022 05 03 TC	1.1	03 May 2022
Patient Information Materials SWiFT Parent+Guardian Consent Form_v1.1_2022 05 03 Clean	1.1	03 May 2022
Patient Information Materials SWiFT Parent+Guardian Consent Form_v1.1_2022 05 03 TC	1.1	03 May 2022
Patient Information Materials SWiFT Information Sheet 6-10 years_v1.1_2022 05 03 Clean	1.1	03 May 2022
Patient Information Materials SWiFT Information Sheet 6-10 years_v1.1_2022 05 03 TC	1.1	03 May 2022
Patient Information Materials SWiFT Information Sheet 11-15 years_v1.1_2022 05 03 Clean	1.1	03 May 2022
Patient Information Materials SWiFT Information Sheet 11-15 years_v1.1_2022 05 03 TC	1.1	03 May 2022
Evidence of Insurance EHAAT		

Evidence of Insurance KSS		
Grazia_Antonacci_CV_03_2022		
Information supplied before REC meeting by EL 2022 03 22		22 March 2022
Research CV - Scott Beattie		
SWiFT Implementation Study_Consent Form_v1.1_2022_04_22_Clean	1.1	22 April 2022
SWiFT Implementation Study_Consent Form_v1.1_2022_04_22_TC	1.1	22 April 2022
SWiFT Implementation Study_Consent Form_v1.1_2022_04_22_TRACKED CHANGE	1.1	22 April 2022
SWiFT Implementation Study_PIS - HCP Focus Group 1_v1.1_2022_04_22_Clean	1.1	22 April 2022
SWiFT Implementation Study_PIS - HCP Focus Group 1_v1.1_2022_04_22_TC	1.1	22 April 2022
SWiFT Implementation Study_PIS - HCP Focus Group 1_v1.1_2022_04_22_TRACKED CHANGE	1.1	22 April 2022
SWiFT Implementation Study_PIS - HCP Focus Groups 2-6_v1.1_2022_04_22_Clean	1.1	22 April 2022
SWiFT Implementation Study_PIS - HCP Focus Groups 2-6_v1.1_2022_04_22_TC	1.1	22 April 2022
SWiFT Implementation Study_PIS - HCP Focus Groups 2-6_v1.1_2022_04_22_TRACKED CHANGE	1.1	22 April 2022
SWiFT Implementation Study_PIS - HCP Interviews_v1.1_2022_04_22_Clean	1.1	22 April 2022
SWiFT Implementation Study_PIS - HCP Interviews_v1.1_2022_04_22_TC	1.1	22 April 2022
SWiFT Implementation Study_PIS - HCP Interviews_v1.1_2022_04_22_TRACKED CHANGE	1.1	22 April 2022
SWiFT Implementation Study_PIS - Patient Donor Focus Group_v1.1_2022_04_22_Clean	1.1	22 April 2022
SWiFT Implementation Study_PIS - Patient Donor Focus Group_v1.1_2022_04_22_TC	1.1	22 April 2022
SWiFT Implementation Study_PIS - Patient Donor Focus Group_v1.1_2022_04_22_TRACKED CHANGE	1.1	22 April 2022
Research protocol or project proposal [SWiFT Trial Protocol_v1.1_03.05.2022 Clean]	1.1	03 May 2022
Research protocol or project proposal [SWiFT Trial Protocol_v1.1_03.05.2022 TC]		03 May 2022
SWiFT_GP Letter_EQ5D5L referral_v1.0_2022 05 03		03 May 2022
SWiFT_GP Letter_v1.1_2022 05 03	1.1	03 May 2022

Membership of the Committee

The members of the Confidentiality Advisory Group who were present at the consideration of this item are listed below.

Please do not hesitate to contact me if you have any queries following this letter. I would be grateful if you could quote the above reference number in all future correspondence.

With the Group's best wishes for the success of this project.

Yours sincerely

Kathleen Cassidy
Confidentiality Advisor

On behalf of the Health Research Authority

Email: cag@hra.nhs.uk

Included: List of members who considered application
Standard conditions of support

Copy to: oxfordc.rec@hra.nhs.uk

**Confidentiality Advisory Group meeting attendance
24 March 2022**

Members present:

<i>Name</i>	
Dr Tony Calland MBE	CAG Chair
Dr Martin Andrew	CAG member
Dr Malcolm Booth	CAG member
Mr Tony Kane	CAG member
Dr Harvey Marcovitch	CAG member
Mr Andrew Melville	CAG member
Ms Rose Payne	CAG member
Professor Sara Randall	CAG member
Mr Dan Roulstone	CAG member
Ms Clare Sanderson	CAG alternative vice-chair

Also in attendance:

<i>Name</i>	<i>Position (or reason for attending)</i>
Ms Katy Cassidy	HRA Confidentiality Advisor
Ms Natasha Dunkley	HRA Head of Confidentiality Advice Service
Dr Paul Mills	HRA Confidentiality Advice Service Manager
Mr Michael Pate	HRA Confidentiality Advisor
Ms Caroline Watchurst	HRA Confidentiality Advisor

Standard conditions of support

Support to process the specified confidential patient information without consent, given by the Health Research Authority, is subject to compliance with the following standard conditions of support.

The applicant and those processing the information under the terms of the support will ensure that:

1. The specified confidential patient information is only used for the purpose(s) set out in the application.
2. Confidentiality is preserved and there are no disclosures of information in aggregate or patient level form that may inferentially identify a person, nor will any attempt be made to identify individuals, households or organisations in the data.
3. Requirements of the Statistics and Registration Services Act 2007 are adhered to regarding publication when relevant, in addition to other national guidance.
4. All staff with access to confidential patient information have contractual obligations of confidentiality, enforceable through disciplinary procedures.
5. All staff with access to confidential patient information have received appropriate ongoing training to ensure they are aware of their responsibilities and are acting in compliance with the application detail.
6. Activities must be compliant with the General Data Protection Regulation and relevant Data Protection Act 2018.
7. Audit of data processing by a designated agent is facilitated and supported.
8. The wishes of patients who have withheld or withdrawn their consent are respected.
9. Any significant changes (for example, people, purpose, data flows, data items, security arrangements) must be approved via formal amendment prior to changes coming into effect.
10. An annual review report is submitted to the CAG every 12 months from the date of the final support letter, for the duration of the support.
11. Any breaches of confidentiality around the supported flows of information should be reported to CAG within 10 working days of the incident, along with remedial actions taken/to be taken. This does not remove the need to follow national/legal requirements for reporting relevant security breaches.