

Amendment request form

Use this template to submit an amendment to an approved application. The completed template will be reviewed by the Confidentiality Advice Team who will then confirm the appropriate action. The Confidentiality Advice Team can be contacted prior to completion to advise on whether the nature of the change requires a formal amendment. Supporting documentation can be used in conjunction with this form.

Please note that support for amendments will not come into effect until a final approval letter is provided.

PIAG/ECC/CAG reference number:	22/CAG/0050
Full 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 – SWIFT
Application type: research or non-research	Research
Amendment date	17/02/2025

1. Please indicate the nature of the change below.

- ☐ Data flows
- ☐ Data items
- ☐ Data sources (see question 4)
- ☐ Purposes of application
- ☐ Data controller (please note that an amended application form and supporting documents setting out the new data controller arrangements will be required, you are advised to contact the Confidentiality Advice Team prior to submission)
- ☒ Data processor (required to have satisfactory security assurances in place - see question 6)
- ☒ Duration amendment
- ☐ Other (please specify):

2. Please summarise the change to the application, specifying how the amendment differs from the detail of the original application:

In the original application, participants with informed consent (either professional legal representative, personal legal representative, patient informed consent) or section 251 support, patient identifiable information would be shared with the Trauma Audit Research Network (TARN). This linkage would enable NHSBT to share that data with TARN, and NHSBT receiving injury data on participants in the study.

TARN was hosted by the University of Manchester, and were subject to a cyberattack. The registry data had not been available for over a year.

TARN has been dissolved, and the data is now held in the National Major Trauma Registry (NMTR), part of NHS England.

The only change is administrative as trauma injury data is now managed by NHS England.

The sample size has been increased to 900 from 848, which has been approved by the HRA, REC and MHRA.

3. Please confirm the justification for the amendment. This should explicitly include the following:

- the reason why it is in the public interest for the amendment to proceed
- the benefits that the amendment will, or is expected to, provide
- The time period for which the amendment is expected to be required
- The consequences if the amendment did not go ahead

It is in the public interest as the research study in this important area of pre-hospital data will go ahead as planned.

The benefits are that the results may show that there is a better treatment regimen to save the lives of injured patients.

The amendment will stand until the end of the study (expected July 2025).

If the amendment did not go ahead, the research study would be unable to continue and the outcomes will not be known. Whole blood is a new component developed over years at NHS Blood and Transplant for patients who are bleeding to death pre-hospital. It would be frustrating for the Sponsor, teams and patients who took part, especially as the study is now in the final phase (recruitment ended in September 2024).

4. If amending the data sources, has the data controller for this agreed in principle for this access to be provided? Please provide evidence of any authorization.

NHS Blood and Transplant as the Sponsor and the NMTR have agreed for access to be provided and contracts are being updated.

5. It is a requirement of the Regulations that an application cannot be inconsistent with the principles of the General Data Protection Regulation and Data Protection Act 2018 (GDPR/DPA). The first principle of the DPA requires that reasonable efforts are made to inform data subjects of the use of their data. The nature of the change may mean that there is a need to update the current information provided to patients. Please confirm whether patient information materials (websites, leaflets, posters etc.) have been updated to reflect the change and detail the changes below.

If no change is intended to be made, please specify the reasons for this decision.

There is no change to be made, as TARN was dissolved after the cyberattack into NMTR. The same dataset exists and continues to be collected from NHS Trusts as before.

The study has completed recruitment and no patient facing materials need to be changed.

6. All applicants processing confidential patient information under the Regulations are required to provide evidence of suitable security arrangements via agreed routes. This must be in place before any support can come into effect, must be maintained for the duration of the support and is expected to be up to date and (in England) reviewed by NHS England at each annual review.

Security assurance is required in relation to ALL organisations involved in processing confidential patient information. Please carefully assess where the processing is taking place, and provide security assurance based upon the jurisdiction and organisation where the information is being processed. Applicants may need to provide more than one security assurance depending on the jurisdiction information is processed, or if processing of identifiable information is taking place in more than one organisation.

Health Research Authority

Processing takes place in:	England	Wales	Scotland
Security assurance provided by:	Data Security and Protection Toolkit (DSPT) – by organisation or specific function	Caldicott Principles into Practice (CPIP) report/or Welsh Information Governance Toolkit – by organisation	Review by the Public Benefit and Privacy Panel for Health & Social Care
Applicant should contact:	Exeter.Helpdesk@nhs.net	The Confidentiality Advice Team (CAT) cag@hra.nhs.uk	Public Benefit and Privacy Panel (PBPP) for Health & Social Care
How assurance is provided to CAG	1. Organisational self-assessed completion of relevant DSPT. 2. Applicant contacts Exeter Helpdesk to request NHS England to review the relevant DSPT self-assessed submissions 3. NHS England review the DSPT submission and confirm to CAG when 'Standards Met'	Relevant CPIP out-turn report/Welsh IG toolkit provided directly by DHCW to CAG	An approval letter from PBPP, where processing is taking place in Scotland, is accepted as evidence of adequate security assurance.

For applicant completion:

Please list all organisations physically processing relevant information without consent for which security assurance is required. Security assurance is provided through NHS England DSPT team reviewing the self-assessed submission. Please ensure you have contacted NHS England and asked them to review your submission. The annual review will not be valid until NHS England has reviewed the submission and confirmed its status as 'standards met'.

If confidential patient information is being processed by NHS England (previously NHS Digital), please select this box: ☒

Security assurance has already been provided for NHS England (previously NHS Digital) so please do not complete any details below for NHS England (previously Digital).

Organisation (Full name)	ODS Code	Date self-assessment submitted to NHS England	Date NHS England confirmed assessment

Health Research Authority

			reached 'Standards Met
National Major Trauma Registry – NMTR (established by NHS England)		n/a as processed by NHS England	n/a as processed by NHS England
NHS Blood and Transplant (NHSBT)	T1460	2019	29/03/2019 Standards met confirmed annually; last check 18/06/2024 approaching standards

Is any processing of identifiable information taking place in Wales? No

Is there any processing of identifiable information taking place in Scotland? No

If processing of confidential patient information is taking place in Wales or Scotland, please contact the Confidentiality Advice Team for advice on next steps. n/a

7. If a research application, has an amendment to a Research Ethics Committee been submitted? Please provide supporting documentation/date to be reviewed/favourable ethical opinion.

This has been prepared and is with the CI and Sponsor for signature. It will be submitted week beginning 03/02/2025.

8. Confirmation of contact details

Please confirm contact details for the purpose of our publicly available register of approved applications.

Applying organisation: NHS Blood and Transplant

Contact Name and role: Professor Laura Green, Chief Investigator

Full address: NHS Blood and Transplant Colindale Centre, Colindale Avenue, Colindale, London, NW9 5BG

Telephone: 07720275360

Email: laura.green@nhsbt.nhs.uk

Information Guardian/Chief Investigator Name: Professor Laura Green

Signed:



Date: 27/02/2025

This form should be submitted, in conjunction with any relevant supporting documentation, to cag@hra.nhs.uk. If you require any assistance in completing this form you are advised to contact the Confidentiality Advice Team on cag@hra.nhs.uk.

Once submitted the form will be reviewed by the Confidentiality Advice Team in the first instance who will confirm whether the amendment is valid or if further information is required